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S. HRG. 109–457

TO REVIEW BIOSECURITY PREPAREDNESS AND EFFORTS TO ADDRESS AGROTERRORISM THREATS

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED NINTH CONGRESS

FIRST SESSION

JULY 20, 2005

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry

Available via the World Wide Web: http://www.agriculture.senate.gov

U.S. GOVERNMENT PRINTING OFFICE

22–648 PDF WASHINGTON : 2006

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
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TO REVIEW BIOSECURITY PREPAREDNESS AND EFFORTS TO ADDRESS AGROTERRORISM THREATS

WEDNESDAY, JULY 20, 2005

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 10:02 a.m., in room SR–328a, Russell Senate Office Building, Hon. Saxby Chambliss, chairman of the committee, presiding.

Present or submitting a statement: Senators Chambliss, Roberts, Thomas, Dayton, Cochran, and Salazar.

STATEMENT OF HON. SAXBY CHAMBLISS, A U.S. SENATOR FROM GEORGIA, CHAIRMAN, COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

The CHAIRMAN. Good morning. I welcome you this morning to this hearing to review the efforts by public and private entities to increase biosecurity and agroterrorism preparedness. I appreciate our witnesses and members of the public being here to review this very important topic as well as those who are listening through our web site. Agriculture is a significant sector within the U.S. economy, accounting for 13 percent of the U.S. gross domestic product and 18 percent of domestic employment. A deliberate attack on the U.S. food supply and agriculture operations would cause severe economic loss from farm to plate.

As we have seen with naturally occurring plant and animal disease, these losses could be particularly severe where States where animal and crop production is connected and largely responsible for the majority of economic activity. For example, three states, Arkansas, Alabama, and my home State of Georgia account for 31 percent of the chickens produced in the United States. North Carolina, Iowa, and Minnesota account for 53 percent of hog production; and five others, Nebraska, Missouri, Oklahoma, Texas, and California produce 35 percent of the cattle. Four States, Illinois, Iowa, Nebraska, and Minnesota produce 54 percent of the corn; and three of those, Illinois, Iowa and Minnesota, produce 39 percent of all soybeans.

Current Federal efforts to prevent and respond to a terrorist attack are governed by two main Presidential directives. We will hear testimony from representatives of the Department of Agriculture, Department of Homeland Security, and the Food and Drug Administration outlining existing efforts and capabilities and what

we must do to deter, detect, and respond effectively to an attack. I am particularly interested in hearing a status report on the implementation of Homeland Security Presidential Directives 7 and 9 and what, if any, additional authorities are necessary to prevent and deter a terrorist attack on the food supply.

While the Homeland Security Act of 2002 and the Bioterrorism Act of 2002 increased biosecurity efforts, it is clear that more needs to be done. This hearing will serve as a useful dialog as this committee works with Senators Burr and Enzi and members of the Health Committee in drafting follow-up legislation to the Project Bioshield Act passed and signed by the President last year.

And while we are talking about that, I want to take a minute to commend the leadership of Senator Burr in this respect. He was a colleague and friend of my mine in the House. He was a leader during his House days, and now he has brought that same leadership and that knowledge and experience to the Senate and is providing real positive direction on this issue.

As we will hear, the responsibility to counter an agroterrorist attack spans the various agencies with different regulatory functions; however, a new partner and often overlooked component in any response is the integration of national and local law enforcement agencies. A recent symposium on agroterrorism hosted by the Federal Bureau of Investigation highlighted the need for our nation to respond quickly and to ensure local producers and first responders are a part of any national response plan. I welcome our colleagues from the law enforcement community to the Agriculture Committee and look forward to your testimony.

As anyone in agriculture knows, farmers, ranchers, extension agents, and many others are an integral part of detecting and responding to any disease outbreak, whether naturally occurring or deliberate. The second panel highlights this important partnership between public and private sectors, and we will hear what is being done to increase our preparedness at the local level in coordination with farmers and ranchers, the scientific community, and industry. No effort to prepare for an attack can be successful without a healthy and strong public-private partnership.

This will be the third hearing in the Senate since 1999 devoted to biosecurity and agroterrorism. My friend and colleague, Senator Roberts, who is with us this morning, held the first hearing in 1999. I think it is fair to say that he recognized early on the need to address the issue and, in his capacity as Chairman of the Senate Intelligence Committee, has continued to highlight the need for direction relative to this issue.

The events of September 11, 2001, propelled the Government into action and forced the Federal agencies to re-think the threats facing agriculture and the need to take steps to prevent agroterrorist attacks. Later, Senator Talent, also a member of this committee, highlighted the importance of the topic at a hearing before the Homeland Security and Government Affairs Committee chaired by Senator Collins almost 2 years ago. I look forward to working with members of this committee to make sure that this aspect of homeland security receives the attention and the resources it deserves. To do otherwise would place a critical sector of the economy at risk.

Before we proceed, I would like to request unanimous consent to insert testimony submitted by the Environmental Protection Agency for the record, and without objection, that will be done.

[The EPA statement follows:]

The CHAIRMAN. I would ask my colleagues, Senator Thomas, Senator Roberts, if you would like to make any opening statement at this point.

Senator THOMAS. Mr. Chairman, I thank you for having this. This is an important issue. I have no statement. I am anxious to hear the testimony.

The CHAIRMAN. Senator Roberts.

Senator ROBERTS. Mr. Chairman, thank you. I also would like to hear from the witnesses, but I do have an opening statement.

STATEMENT OF HON. PAT ROBERTS, A U.S. SENATOR FROM KANSAS

Senator ROBERTS. Let me just say thank you for your very kind remarks and for holding this hearing. This is one of the most important issues that we face in agriculture, and it is true back in 1999, as Chairman of the Armed Services Subcommittee on Emerging Threats, we held it so important that it we held it in the Armed Services Committee. That was the first hearing on the topic, and at that time, our president of Kansas State University testified on the real need and urgency to really try to accelerate the research and response to efforts in this area. I argued at the time that this was a topic we couldn't ignore because it was simply too easy a target and would create absolute havoc and chaos in our food supply and our ag markets if it were to occur.

You know, at first, quite a few people wanted to ignore the issue or at least they didn't want me to talk about the issue. I know on one visit to western Kansas, I had a farmer come up to me and say, Pat, you have got to quit talking about all this agroterrorism stuff; you are scaring the dickens out of people here and you are hurting the markets. Actually, he put it a little more colorfully than that, but I think you get the picture. That was the reaction I got until the tragic events of 9–11. Obviously, we started to pay a lot more attention after that.

We have since learned that several of the 9–11 hijackers had agriculture training. I think four of them—no six, and we know that they had an interest in crop dusters. It is my belief those crop dusters may have never been intended for people, but possibly could be used on agriculture. The threat is real. We know the former USSR had worked to try and simply weaponize many agriculture diseases, including foot and mouth disease and glanders and wheat rush, just to name a few. In many instances, these stockpiles still remain in loosely guarded facilities. That is what the non-limiter program is all about, and we don't know whose hands some of it may have ended up in.

We traveled to Ordzhonikidze in Russia to take a look. That was one of the centers where if you looked at what they were making, it gave a real true picture, I think, of what President Ronald Reagan said in terms of the evil empire in terms of what they were making in terms of stockpiles. By the way, you didn't open up any

refrigerator doors and take a good look or take a breath. Then they invited you for lunch, which made you think a little bit.

I sit here today as Chairman of the Senate Intelligence Committee, and I can tell you that while we have no details of a specific threat against the food and agriculture sectors, as my colleague who sits in and is a valued member of that committee knows, but an attack is certainly possible, if not probable. It is so easy to do. In many instances, in the case of foot and mouth disease, it takes little, if any, scientific training. You just put a handkerchief under a diseased animal in Afghanistan, put it in a zip-lock bag, put it in your suitcase, come to the United States and drop it in any one of our feed lots, and we are in a lot of trouble.

[Telephone interruption.]

The CHAIRMAN. That is the Kansas State fight song, in case anybody missed that.

Senator ROBERTS. Actually, I tried to put the Marine Corps hymn on there, but I haven't got it done yet. And my wife is not going to be pleased that I just cut her off. She is, in fact, the speaker of my house.

I am pleased since 9–11 we have made major strides in this area. We have created new diagnostic networks. We have increased research. Most importantly, our intelligence agencies and also our relevant food and agriculture agencies are talking to each other and sharing information. We have come a long way.

A terrorist attack on the ag sector, as you know, Mr. Chairman, need not be large in scale to have a devastating impact on our markets. Simply put, we cannot allow that to happen, and that is why I thank you again for holding this hearing today. So thank you and I look forward to the testimony of our witnesses.

The CHAIRMAN. Thank you, Senator. We are now joined by Senator Dayton.

Senator Dayton, do you have any opening comments you wish to make?

Senator DAYTON. I wish I could slim down the way this table did. Other than that, no, but you fooled me.

The CHAIRMAN. Thank you. We are glad you are here.

Our first panel this morning consists of the following individuals: The Honorable Charles Conner, Deputy Secretary of the United States Department of Agriculture.

Chuck, I am glad we got you confirmed because you have been a busy guy and you have spent a lot of time over here with us, which we appreciate and we are glad to have your expertise and your knowledge here this morning.

Maureen McCarthy, Director, Office of Research and Development from the Department of Homeland Security. Dr. McCarthy, welcome.

Mr. John Lewis, Deputy Assistant Director, Counterterrorism Division of the Federal Bureau of Investigation. Mr. Lewis, welcome.

Dr. Robert Brackett, Director, Center for Food Safety and Applied Nutrition from the Food and Drug Administration. Dr. Brackett, we certainly welcome you here this morning.

We will certainly insert your full statement in the record, but we will turn to each of you now. We will start with Chuck and move

down this way. Any opening comments you wish to make, we look forward to hearing from you.

Chuck.

STATEMENT OF CHARLES CONNER, DEPUTY SECRETARY, U.S. DEPARTMENT OF AGRICULTURE, WASHINGTON, DC

Mr. CONNER. Mr. Chairman, thank you for this opportunity to be here today. I appreciate the invitation and the opportunity to represent the Department of Agriculture on this very timely hearing.

Today, the committee raises an important issue, food and agricultural security. It is an issue that the U.S. Department of Agriculture considers essential to our mission. We seek to provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management. In light of the recent global events and the growing focus on the security of our food and agricultural systems, we appreciate the opportunity to provide you with an update on USDA's homeland security-related efforts.

I have summarized at your request, Mr. Chairman, my testimony to 5 minutes, but I would ask unanimous consent that my entire testimony be included in the record.

The CHAIRMAN. Without objection.

Mr. CONNER. This year, agriculture exports, as you know, are projected to reach approximately $59 billion, thereby making 2005 the third largest export sales year in our history. Our nation's food system contributes almost $1.24 trillion or over 12 percent to our gross domestic product, and it employs approximately 17 to 18 percent of our entire workforce, as you have noted, Mr. Chairman. With such a large stake in our nation's economy, agriculture and the security of our agricultural sector is our No. 1 concern.

As a department, we face many challenges in protecting this important infrastructure. The food and agriculture sector is particularly vulnerable to threats because agribusiness is not constrained by political boundaries and, as we all know, diseases and pathogens do not acknowledge State or national borders. The collective nature of the global food system is our strength, but it is also a disadvantage in the event of an attack or natural disease outbreak. Additionally, one of the agricultural sector's greatest contributions to the quality of life is the fact that our products flow quickly and easily via interstate commerce. Contaminated products, whether intentionally contaminated or unintentionally contaminated, could spread a pest, disease, or other agent very quickly and have a devastating effect on our economy.

Since September 11, 2001, USDA has made great progress to focus and expand our mission to include security for the first time. What has not changed is our conviction that the threat to agriculture is very real. We believe that the department is playing a critical role in protecting the nation's food supply. Chairman Chambliss, our intention is to be proactive in maintaining a safe food supply and excellent detection mechanisms for animal and plant diseases and to be on the forefront of research and development to identify, contain, and eradicate animal and plant threats before they are able to have a major impact on our agricultural systems or our nation's economy.

USDA remains committed to sustaining the strong relationships we have established with our partners on the Federal level as well as with the State and local governments. Our work with the Department of Homeland Security, the Department of Health and Human Services, and other agencies is absolutely paramount. Additionally, we have taken broad measures to educate producers, processors, and consumers on the importance of identifying and preventing security threats. We realize that protecting America's food supply is a momentous task, and that is why we value the opportunity to work in partnership with other agencies, governments, including this committee, suppliers and consumers on maintaining a secure food supply.

My submitted testimony will also highlight the advances that the department is making to implement both Homeland Security Presidential Directive 7 as well as 9 from our focus on surveillance and monitoring diseases and outbreaks to response and recovery following an incident. USDA is thoroughly implementing the HSPD directives. We will continue to work closely with other agencies to ensure that we have the safest agriculture and food supply in the world.

The CHAIRMAN. I thank you for holding, again, such a timely hearing, and after my colleagues' testimony, I would be happy to respond to questions the committee may have.

[The prepared statement of Mr. Conner can be found in the appendix on page 44.]

The CHAIRMAN. Thank you very much, Mr. Conner.

Dr. McCarthy.

STATEMENT OF MAUREEN McCARTHY, PH.D., DIRECTOR, OFFICE OF RESEARCH AND DEVELOPMENT, DEPARTMENT OF HOMELAND SECURITY, WASHINGTON, DC

Ms. MCCARTHY. Good morning, Chairman Chambliss, Senator Harkin, and distinguished members of the committee. I am very pleased to appear before you today to discuss the progress the Science and Technology Directorate of the Department of Homeland Security is making in close cooperation with our other agency partners to increase the Nation's ability to prevent, protect, against, and respond to acts of bioterrorism against our agriculture and food supply.

Last week, Secretary Chertoff announced a six-point agenda to enhance the department's ability to manage risks, prioritize policy, share information, and conduct operations with a strong focus on preparedness. We must accomplish our mission with a continued sense of urgency. Our enemies constantly change and adapt. So we as a department must be nimble and decisive. We are adopting a risk management approach which integrates threats, vulnerabilities, and consequences to prioritize our actions and assess our performance.

A major initiative of the department is the integration of activities that increase the Nation's preparedness against present and future threats. Protecting the Nation's agriculture and food supply is a critical element of these efforts. Our work must be guided by the understanding that effective security is built upon a network of systems that spans all levels of government and the private sec-

tor. DHS does not own or control all of these systems. We must set a clear national strategy and design an architecture in which separate roles and responsibilities for security are fully integrated amongst the public and private stakeholders.

We must draw on the strength of our considerable network of assets, functioning as seamlessly as possible with other Federal agencies, State and local leadership, law enforcement, emergency management personnel, first responders, the private sector, our international partners, and the general public. Building effective partnerships must be at the core of every mission of the department.

The Science and Technology Directorate is responsible for a broad range of agrodefense, research, development, test evaluation, and facility operations. These include accelerating the development of new veterinary countermeasures, establishing new university centers of excellence for agriculture and food security, and developing in close coordination with USDA a plan to provide facilities for farm animal disease and zoonotic defense, diagnostics, forensics, training, and countermeasure develop.

The S and T Directorate in partnership with USDA has developed a joint strategy and program for farm animal disease defense with an initial focus and emphasis on the development of veterinary countermeasures for foot and mouth disease. Within this strategy, ARS from USDA leads the basic research and early development of diagnostics, vaccines and immunomodulators. Promising countermeasure candidates are then transferred to DHS for targeted advance development in cooperation with industry. The overall goal of this work is to expedite the transition of new validated diagnostic tools to the national animal health laboratory network and new vaccines and immunomodulators to the national veterinary stockpile.

A significant achievement of our agricultural security preparedness program was the establishment of two new university homeland security centers of excellence. Through these homeland security centers and their extensive networks, we are engaging both the research and education capabilities of the Nation's academic community to protect our agricultural security and food infrastructure.

The Plum Island Animal Disease Center is a unique and critical facility for the Nation's foreign animal disease defense. To facilitate overall coordination of the programs and operations of Plum Island, a board of directors has been established which is chaired by DHS and has the administrators of both ARS and APHIS as members. In 2004, Plum Island celebrates its fiftieth anniversary. The facility is now well beyond its originally planned life span and is in need of recapitalization. This year , we are conducting a conceptual design study for the next generation of a biological and agro facility. This process involving gathering requirements and developing options for the state-of-the-art facility that will support the Nation's critical mission to protect our agriculture infrastructure well into the twenty-first century. The study is being done in collaboration with USDA and HHS.

The Secretary is committed to enhancing our preparedness and protecting the critical agriculture infrastructure. This is a high-priority mission for the department and one we conduct in strategic

partnerships with our colleagues from USDA, other government agencies, and the private sector.

This concludes my prepared statement, and with the committee's permission, I request my formal statement be submitted to the record. Mr. Chairman, and all the members of the committee, I thank you for the opportunity to appear before you and would be happy to take any of the questions you may have.

[The prepared statement of Ms. McCarthy can be found in the appendix on page 58.]

The CHAIRMAN. Thank you, Dr. McCarthy. Your statement will be put into the record.

We now turn to Mr. Lewis.

STATEMENT OF JOHN E. LEWIS, DEPUTY ASSISTANT DIRECTOR, COUNTERTERRORISM DIVISION, FEDERAL BUREAU OF INVESTIGATION, WASHINGTON, DC

Mr. LEWIS. Good morning, Chairman Chambliss, Senators. Thank you for the invitation to come today and discuss with you this topic of agroterrorism.

Since the tragedy of 9–11, the FBI has necessarily sharpened its focus on unconventional methods of future terrorist attacks, including a potential for some manner of terrorist event aimed at our food or ag sector, but mainly the previous and much publicized terrorist events including the Oklahoma City bombing, 9–11, Madrid, and now just recently London. We must make it our business not to let these series of events create for us something of a pattern that might preclude the type of proactive activity needed to prevent the next event.

Most people do not equate terrorist attacks on people, public transportation, and buildings with attacks on plants and animals. We understand this threat to be real and we know the impact can be could be devastating. Our gathering here this morning is important. It sheds light on an area of our work that, frankly, is not all that often the leading topic around the terrorism discussion table.

The absence of any direct attack on our food supply does not minimize the possibility that such an event could occur. We know from the body of intelligence collected to date that al Qaeda is aware of our agriculture industry along with other potential targets. To counter this particular terrorism threat, whether from an international or domestic terrorist, we are actively engaged and growing more so with our counterparts, not only across government, but across industry to share information, technology, and resources. Let me touch on some of these areas.

One of the ways we are collaborating is through an entity known as the Agricultural Intelligence Working Group. Members of this group from across the U.S. intelligence community and beyond meet regularly to exchange information and ideas about food security and how best to maximize our combined skills, technology, and resources. The FBI is also a member of the National Bioforensic Analysis Center. This center is one of four components of the National Biodefense Analysis and Countermeasure Center. We are working with multiple Federal partners in the area of case attribution, that is identifying and exploiting any signatures or characteristics of a biological agent.

The second group identified is a scientific working group on microbioforensics led by our laboratory division down in Quantico. It is engaged, again, with our Federal partners in multiple areas of research, the results of which all can be used 1 day to improve the tool set we rely upon to carry out our counterterrorism mission.

In addition to partnerships that begin here inside the beltway, we are expanding our partnerships to include those in industry. We are reaching out to farmers, cattle ranchers, food producers, and distributors, among others. In the Counterterrorism Division here at FBI headquarters, we are directing the formation of a program called Agri-Guard as well as the formation of agroterrorism working groups nationwide. The Agri-Guard program will be modelled after our existing Infraguard initiative. The Infraguard initiative was started back in 1996 and today serves as a virtual and secure link with a vetting national membership of approximately 12,000 representatives of companies throughout the U.S., representing not only the computer industry for which this was started, but beyond.

Using the Infraguard technology backbone, we are moving forward today to create this very same informational exchange within the food and ag sector. We have the money and resources now dedicated to this task, and we are working with our Federal partners to maximize the degree of coordination that both the States and industry expect from us.

Beyond this initiative, just in the past several year weeks, I communicated with our 56 field offices and directed each to establish formal agroterrorism working groups within their respective territories. This directive will lead to a more formal and recurring meeting of key figures from the food and ag sector in each of the 56 field office territories. Although some of this is already in place in certain areas of the United States, my intention is to strengthen and to a degree standardize our partnerships across the country. We are working with our Federal partners and looking forward to recognizable progress in this area by bringing together on a regular basis for the purposes of prevention, awareness, intelligence, investigative response, and crisis management, State-level groups whose membership will include the State Secretary of Agriculture , for instance, the State's chief veterinarian, leading law enforcement figures, public health officials, and pertinent representatives of the food and ag sector.

If I may depart just for a moment, I can tell you that from the State of Georgia as well as from your State, Senator Roberts, we have outstanding participation from across the food and ag sector, and, frankly, we could use those as models to push out to the rest of the country for how to bring these groups together.

On another front, the FBI has partnered with DHS, USDA, FDA, and private industry to conduct site surveys of specific and significant food and ag sites throughout the United States. I call this program the Strategic Partnership Program. The aim of this initiative conducted closely with our industry counterparts is to bring together subject matter experts whose analysis of a specific site can lead to the identification of potential vulnerabilities that could represent the opening a terrorist might exploit to plan for and carry out some sort of attack. This project is also intended to educate and raise a level of awareness of area law enforcement, lead to the de-

velopment of intelligence collection strategies around these sites and/or vulnerabilities, and to facilitate discussions and planning to develop mitigation strategies for early detection, deterrence, disruption, interdiction, and prevention. The sites will include the entire production cycle from farm to fork.

Finally, the FBI today operates 105 joint terrorism task forces geographically dispersed throughout the United States. As you probably know, each of these are comprised of municipal, county, State, and Federal law enforcement personnel. These JTTFs are the focal point for counterterrorism efforts here in the United States and respond to all manner of threats.

The JTTFs in each field office are aided by highly trained WMD coordinators, weapons of mass destruction coordinators. Each of these WMD coordinators maintain their own liaison network within law enforcement and public safety personnel and in their respective territories, and it is through this network that all manner of information passes. The WMD coordinators are, in turn, closely connected to our headquarters-based WMD domestic terrorism section where substantive multi-discipline scientific guidance and expertise is available 24–7. If we don't have the scientific guidance resident at FBI Headquarters, our WMD team maintains an excellent array of partnerships across the community, including those folks seated here today that we can get answers from.

We also operate the hazardous materials response unit and 27 strategically located hazardous materials response teams throughout the United States. These response capabilities significantly enhance our ability to collect samples and effectively support threat assessments when needed.

Farmers, ranchers, food distributors and producers are as much a first line of defense as our efforts need to be. If a rancher sees unusual symptoms of illness in a herd, if a food distributor notes suspicious activity in one of their distribution centers, we must be able to rely upon rapid and effective coordination so that all of us, including those here at the table who may be potentially involved, have the head start we need. All of us here are working to improve that.

Our goal is to impress upon those in the food and ag sector, and, frankly, those of us who need to work closely with them, of the need for increased cooperation, increased awareness, and the recognition that given the prevailing threat conditions, we need to chart in a more collaborative course. We have been met with excellent cooperation from all areas of the food and ag sector where we have been recently. I am very optimistic that as we work here to improve our own positions, the food and ag sector is ready, willing, and able to fully cooperate with us and where needed improve theirs.

Thank you, sir. I would be happy to respond to any questions when they come.

[The prepared statement of Mr. Lewis can be found in the appendix on page 67.]

The CHAIRMAN. Thank you, Mr. Lewis.

STATEMENT OF ROBERT BRACKETT, Ph.D, DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION, FOOD AND DRUG ADMINISTRATION, COLLEGE PARK, MARYLAND

Dr. BRACKETT. Good morning, Chairman Chambliss and members of the committee. I am pleased to be here today with my colleagues from the United States Department of Agriculture, the Department of Homeland Security, and the Federal Bureau of Investigation. FDA appreciates the opportunity to discuss our food counterterrorism activities.

A great deal has been done in the last few years to enhance the safety of our food supply. FDA has worked with food safety agencies as well as law enforcement, intelligence gathering agencies, and the private industry to significantly strengthen the Nation's food safety 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 vulnerabilities, the creation of more effective production programs, new surveillance systems, and faster outbreak response capabilities.

FDA is the Federal agency that regulates everything we eat except meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility often extends to live food animals and animal feed, and FDA is also responsible for ensuring that human drugs, human biological products, medical devices, and radiological products, as well as veterinary drugs are safe and effective and that cosmetics are safe.

In our food safety and defense efforts, FDA has many partners: Federal, State, local agencies, academia and industry. We are working closely with our Federal partners such as USDA, DHS, Homeland Security, Counsel to the White House, Department of State, the Central Intelligence Agency, and the FBI, but I want to especially emphasize our close working relationship with our sister public health agency, CDC, Customs and Border Protection at DHS, and USDA's Food Safety Inspection Service. FDA is working closely with DHS and other Federal agencies to implement the President's Homeland Security Presidential Directives, HSPDs. 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.

The HHS and USDA Secretaries or their designees exercise key responsibilities as sector-specific agencies. DHS serves as the coordinator of the food and agricultural sector with HHS and USDA as co-leads for the food sector, and the USDA is the lead for the agriculture sector. This collaborative effort combines expertise from several Federal agencies as well as that of State and local officials and the private sector.

Over the last past 3 years, FDA has been busy implementing the Public Health Security and Bioterrorism Preparedness and Protection Act of 2002. The Bioterrorism Act provided the Secretary of Health and Human Services with significant new authorities to protect the Nation's food supply against the threat of intentional contamination and other food-related emergencies. These authorities improve our ability to act quickly in responding to a threat-

ened or actual terrorist attack as well as well as other food-related emergencies.

I would like to mention just a few of the provisions of the Bioterrorism Act. Section 305 of the Bioterrorism Act requires registration of foreign and domestic food facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the U.S. Thanks to this provision, FDA for the first time has a roster of foreign and domestic food facilities that provide food for American consumers. In the event of an emergency, the registration information will help FDA quickly identify, locate, and notify the facilities that may be affected.

Section 307 requires the submission to FDA of prior notice of food, including animal feed, that is offered for import into the United States. This advance information enables FDA, working closely with CBP, to more effectively target inspections at the border to ensure the safety of imported foods before they move into the U.S.

Section 306 authorizes FDA to access certain records when the agency has a reasonable belief than an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. This enhances FDA's ability to track and contain foods that pose a threat to American consumers from accidental or deliberate contamination of food.

I would like also like to briefly mention a few of our other programs. FDA has issued guidance on the security measures the food industry may take to minimize the risk of food that would be subject to tampering or other malicious criminal or terrorist activities or actions. To increase laboratory surge capacity, FDA has worked in close collaboration with the Food Safety Inspection Service to establish the food emergency response network to include a substantial number of laboratories capable of analyzing food for agents of concern. To enhance coverage of imported food shipments, FDA has expanded FDA's presence at ports of entry, increased surveillance of imported food, increased domestic inspection, and enhanced our laboratory analysis capacity. We have conducted extensive scientific vulnerability assessments of different categories of foods, determining the most serious risks of intentional contamination with different biological and chemical agents during the various stages of food production and distribution.

FDA has established an Office of Crisis Management to coordinate the preparedness and emergency response activities within FDA and with our Federal, State, and local counterparts. We have embarked on an ambitious research agenda throughout FDA to address potential terrorist threats.

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

Thank you for this opportunity to discuss FDA's counterterrorism activities to protect the food supply. I would be happy to respond to any of your questions.

[The prepared statement of Mr. Brackett can be found in the appendix on page 71.]

The CHAIRMAN. Thanks to each of you for those opening comments.

The Government Accounting Office released a report in March reviewing efforts to protect agriculture from terrorist attacks. While the report acknowledges the efforts and progress currently underway at USDA and DHS, it cites certain shortcomings that need to be addressed. Can each witness address what your respective agencies are doing to address the conclusions and recommendations in the GAO report, what corrective actions are being taken in regard to the conclusions of the report?

Dr. McCarthy, I am particularly concerned about the dramatic drop in the number of agriculture inspections following the transfer of inspectors from APHIS to DHS. Has DHS determined the reason or reasons for the decline in inspections, and what is being done to correct the problem?

Mr. Conner, the report also notes the inability of the national veterinary stock pile to respond to a threat like foot and mouth disease within 24 hours. What are the limits to the development of the stockpile and what is needed to address animal disease issues to ensure an outbreak does not spread across a large geographic area and cause catastrophic economic loss?

Ms. MCCARTHY. Thank you, sir, and we will certainly give you a more detailed description of the corrective action plans to the response to GAO for the record, because I would like to get those facts straight for you, and we have taken that report very seriously and have many actions that are undergoing across the department to respond to that.

In particular on your question of inspections, and I will get back, again, the more specific details for you on the record, the approach that the Department of Homeland Security is taking on the inspections, though, is a risk-based approach. So we have increased the inspections on what we consider to be high-risk cargo coming into the country, and that has resulted in potentially less inspections on what we consider to be lower risk things coming into the country. The specifics on the number of inspections that are done at any place, I will certainly get back to you on the record, but I can tell you that the department as a whole has taken the issue of risk management at its core for everything that we do, and that is part of what is driving the changes in the inspection protocols at the borders.

Thank you.

Mr. CONNER. Mr. Chairman, we take the report and the recommendations of the GAO very, very seriously. I think one of the issues they identified for the Department of Agriculture was our stockpile of vaccines, and the issue that we have there is that the department acknowledges that we do not have large stockpiles of the user-ready vaccines, particularly for issues like foot and mouth disease. What we do have, though, are significant stockpiles of the products that are necessary to develop the particular vaccines that will be used in the event that we would have an outbreak.

I believe, Mr. Chairman, that the department is confident that we have contracts with manufacturers where in the event that we

have a particular strain of hoof and mouth disease outbreak in a particular region, we are prepared to analyze that strain very, very quickly and determine the precise vaccine that would be necessary to manufacture that vaccine. We believe our contract specifies that within two or 3 days, you know, we have the ability then to receive the production of the vaccine tailored to that particular event, which can vary. Not all vaccines are applicable to every particular outbreak, and so we have the parent material. We have the contracts in place for the production of the vaccine that become necessary, but then let me also stress that the vaccine part of the control of this outbreak is an important aspect, but it is not the only aspect, and obviously the department continues to rely upon our traditional methods of quarantine and depopulation as the first line of defense in the event that we have a particular outbreak, be it hoof and mouth disease or some other incident.

The CHAIRMAN. Mr. Lewis, Dr. Brackett, do you have a comment on the GAO report?

Mr. LEWIS. Mine is going to be very brief, sir. I am not familiar with this report, but I am going to get a hold of it, and if there is any corrective action required at DOJ or FBI, I will certainly get back to you on that and do so promptly.

The CHAIRMAN. Thank you.

Mr. BRACKETT. Mr. Chairman, although the report dealt primarily with agriculture issues, we looked very closely to find out what parts that we can take lessons from. Several things, one of which is that we do participate on the steering committee on the national veterinary stockpile and although it is primarily being concerned with biologics and vaccines at this time, our Center for Veterinary Medicine, which has oversight over drugs and devices that might be used with animal diseases, is looking to see how that might fit in the future.

Also an important part has to do with communicating what we have learned from the many exercises that we have done over the years, including such things as Top-Off–3, and we are in the process of writing up our lessons learned and contributing that to the DHS web site so that the other agencies can see what our perspective has been on that particular issue.

The CHAIRMAN. OK. Dr. McCarthy, you made mention of the work at Plum Island, which I think we would all agree with you are very much outdated, particularly with respect to the new types of potential biological agents that we need to make sure that we protect our food system from.

Mr. Conner, I will have to tell you there is some apprehension. I have a feeling that Senator Dayton is going to ask you about why we were not able to determine the BSE issue more quickly than we were able to in recent weeks or, actually, recent months, and I am a little bit concerned about the fact that since September 11th, we have spent billions and billions of dollars on the issue of homeland security, but yet we don't have a lab in the United States of America that is capable of making an instantaneous decision on BSE, which is a fairly common disease in livestock. So I am a little bit concerned about where we are going relative to updating Plum Island, building a new lab, or whatever the answer may be to this issue.

And I would appreciate it, Dr. McCarthy, you and Mr. Conner, addressing that a little more in detail.

Mr. CONNER. Well, Mr. Chairman, I will go first. On the issue of Plum Island, I will defer to Dr. McCarthy on that, but I will just simply note that since the transfer of that facility from APHIS over to the Department of Homeland Security in 2003, we have had excellent cooperation with DHS on this. They consult with us. We still have mission areas occurring within the Plum Island facility and the relationship and working together has been a great, and I will let her more specifically address future plans they may have for Plum Island.

On the issue of anticipating Senator Dayton's concern, Mr. Chairman, I will just say the decision to go to Waybridge for the verification, the tests that were completed there, I believe we have the facilities within our laboratory system in this country to conduct the same tests that were conducted in Waybridge, England. In terms of a final call, if you will, in this situation where just for review of the committee, we did have the IHC test, which was negative, and the Western Bott test on the same animal showing positive some months later. We felt in this particular case given the experience that Waybridge has had in this issue because of all of the BSE situations in Europe and in England, which are many times the magnitude of the problems that we have seen here in North America, that we felt it would be best for them to be sort of the referree in the case of this situation where we had two conflicting results.

But I don't believe there was actually any testing done by Waybridge that could not have been conducted in the U.S. if we would have chosen that option, but we felt it was best to go to the one institution that has probably had more experience with this than any place else, and I am thankful that our institutions here do not have a lot of experience in this situation as Waybridge has had.

The CHAIRMAN. HSPD–9 established national policy to protect against terrorist attacks on agriculture and food systems. Specifically, the directive calls for both FDA and USDA to develop vulnerability assessments for agriculture and food sectors. What is the status of these respective assessments and how are the conclusions reached in them helping your agencies develop technology intervention and countermeasures to potential threats? Mr. Conner? Dr. McCarthy?

Ms. MCCARTHY. Thank you, Mr. Chairman. I will touch on the response to HSPD–9 in the context of the previous question on Plum Island as well, because one of the recommendations out of HSPD–9 was to assess the Nation's facility capability to respond to not only our current agricultural mission responsibility, but what we may see as future emerging needs, particularly with agroterrorism.

We at the Department of Homeland Security in close partnership with USDA have taken the issue of ensuring that the Nation maintains the critical national assets that it has in order to be able to be responsive to both the research, the diagnostics, and the operations that are necessary to protect the agriculture of this country. As a result of the studies that we have undertaken in the past and

the assessment that we have undergone with state of the facility at Plum Island, we have underway right now internally a study that will conduct—a feasibility study that will be conducted to assess the requirements the Nation has for agriculture security and in particular the merging of those requirements from agricultural protection and into zoonotic diseases.

We are working right now, we are working with the conceptual study, gathering the requirements in partnership not only with USDA, but also with our colleagues from HHS to determine what is needed in this nation in order ensure that we have that base for the future, the next 50 years. Plum Island has served us well, don't get me wrong, but the facility itself is not really what this is about. It is understanding the capability the Nation needs.

In that respect, we have taken the recommendations of HSPD–9 very seriously and have worked on that particular one in very close partnership with our colleagues from USDA and HHS. We were also tasked in HSPD–9 to reach out to the academic community, and to that end, we have created two university centers of excellence focused on agricultural security. The National Center for Foreign Animal Disease and Zoonotic Defense is led by Texas A & M and is very engaged with our work on developing agricultural countermeasures for not only foot and mouth disease, but Rift Valley Fever, avian influenza, and brucellosis.

We also created the National Center for Food Protection and Defense which is led by the University of Minnesota, and they are very engaged in assessing the vulnerabilities of our food supply and developing mechanisms for modeling and also understanding protection of the nodes in our food supply. We have been engaged extensively with USDA in our joint research and development strategy to enhance the ability of the research community to respond to the emerging needs that we have in agricultural terrorism.

Thank you.

Mr. CONNER. Mr. Chairman, I think I would just echo what my colleague has said, but to put a fine point on it from the Department of Agriculture's standpoint, I am advised we have completed seven assessments through our Food Safety and Inspection Service. I believe four assessments have been completed by APHIS, and I think we are working cooperatively on some others with FDA, obviously for the purpose of then sharing the results of these assessments across not only mission areas within USDA, but the various agencies that are involved in this.

The CHAIRMAN. Senator Thomas and to my colleagues, with just three of us here, we will be a little liberal with the 5–minute rules, unless somebody has a time crunch.

So Senator Thomas.

Senator THOMAS. Thank you, Mr. Chairman.

I guess I have not been involved in this as closely as many have, but we have always had drug inspections to make sure that they are safe. We have had food inspections always. We have always checked things that are imported. Foot and mouth disease is not anything that is new. So I guess I am saying what are the most vulnerable areas? What is new? What are you doing differently? This is on bioterrorism. It has been awfully general, as you said,

things that we have been doing forever. What are the highest priorities now that are different than what you did five to 10 years ago?

Mr. CONNER. Well, I will start out.

Senator THOMAS. You have reacted a little bit to what is being done differently because apparently we are in a different time, but you said a lot of it is not new.

Mr. CONNER. Well, I will start and then turn it over to my colleagues, Senator Thomas. I will speak only from the Department of Agriculture's perspective. What we are doing at the Department of Agriculture is, indeed, new. It is not a same ole-same ole that has been dressed up in now a homeland security package, if you will. The work that we are putting into these assessments, particularly working with the private sector in terms of making these assessments and providing recommendations on how they can help us in protecting the safety of the food supply, I mean the government is not——

Senator THOMAS. You have been doing that for years.

Mr. CONNER. Well, we have been involved in the safety of food in terms of inspection for pathogens, those kinds of situations. What we haven't been involved in is assessing the vulnerabilities of these particular institutions involved in food production, and I can give you a couple of props here, Mr. Thomas, just in terms of activities that would not have been part of anything the Department of Agriculture was doing before.

For example, we have recently published, and I believe shared through the American Trucking Association, guides to security practices for transporting agricultural and food commodities. This is not about safety in the traditional sense of is there e. coli on the meat or something like that. This is about making sure that once those products are put on your truck, that there is no chance of someone or something somehow contaminating those products. This was not done before. This was not a traditional role of the Department of Agriculture.

Through our web site, we have done a number of things. I just brought, again as a prop, brochure, the Threat to the American Livestock Industry that we are publishing. That, again, is not about the traditional methods of contamination, but about how you can make sure that the product that you are sending from farm to table is secure and that there is not an opportunity for those kinds of contaminations, be it intentional but possibly unintentional as well. That type of communication out to the local level has just not been a traditional role of the Department of Agriculture as well.

So certainly, yes, we have always had communication with local people, but it has not been focused upon these threat matrixes as we now have, and this is all new activity for us. I point to the amount of money that has been spent at Ames, Iowa in that facility for upgrading so that we are on the cutting edge in terms of rapid detections of these. I point to the networking that we have among all of our laboratories to share information so that if something is detected in Ames, Iowa, that almost instantaneously a laboratory in North Carolina is aware of that so that they know what to be looking for. All of that kind of instantaneous type of communication and coordination was not present before. So it is new from our standpoint.

Ms. MCCARTHY. Sir, I think you make a very good point, which is the fact that we are leveraging off of a huge base that this country has invested in for many, many years to protect the agriculture of the Nation, no question about it. I think what has happened in particular from the Department of Homeland Security's perspective, is we come with the sense of urgency of what must be done faster, what things must be accelerated and why.

In particular, let me touch on one point, and that is the issue of understanding the difference between a potential natural outbreak and an intentional introduction, for instance the possible intentional introduction of foot and mouth disease into this country. If it is intentionally introduced in multiple places around the country, the potential economic impact could be much greater. Our responses could be overwhelmed much more quickly. So we need to be able to understand whether or not there are different types of responses. We need to be able to apply our tools in ways that haven't been done before because of the sense of urgency.

It is also the matter that it may hop over borders. So the fact that we have FMD-free borders surrounding us may be not the paradigm we are working with now. If the material can, indeed, be put in a plastic bag and carried over from a foreign country and introduced, then our protection strategies may not be as robust.

So we come with a sense of urgency. We come with the notion that we need to accelerate alternative response mechanisms. We also come with the notion that we merge in intelligence, and that is new. We hadn't been in that business in the agricultural business quite as much, and we work very closely now with our partners particularly in the law enforcement community.

We have established for the first time an agricultural forensics capability. That is different from just diagnostics. That is the ability to do forensics in such a way that our law enforcement colleagues could use that information in a court of a law in a prosecution so that we could actually understand quickly who possibly perpetrated an event if it was intentional. That is an additional set of capabilities that we have brought to bear since the sense of urgency came into place with agroterrorism.

Thank you.

Mr. CONNER. Senator Thomas, if I could just add one additional comment to my earlier statement as well, I was reminded that we have worked with FSIS-regulated industries to develop model food security plans for those individual plants, and I believe as of early May of this year, our Agricultural Marketing Service agency that is involved in the substantial procurement of those commodities for various uses within the Department of Agriculture is only procuring commodities from those plants that actually have the security plans in place. Again that is a relatively recent change for us.

Senator THOMAS. Thank you. I guess we need to make it a little more clear to everyone that if this is a different situation, we need to be doing something a little unique and a little different than we have been doing in the past and not simply talk about doing the investigation of drugs and food and everything we have always done. That doesn't seem to show that need for change.

I appreciate it. Thank you.

The CHAIRMAN. Senator Roberts.

Senator ROBERTS. Thank you, Mr. Chairman.

My first question is to Chuck. Chuck, welcome home.

Mr. CONNER. Thank you, sir. Thank you.

Senator ROBERTS. It is good to see you and we appreciate you here for the first time since your confirmation and your swearing in. My first question to you is who is in charge of the food security policy down at the department? I know that Mr. Stump is the head of your homeland security activities at the staff level. Jim Moseley has gone off to Afghanistan and is doing good work over there. I know Secretary Johanns is very interested in this. Is it you? Who is the lead dog?

Mr. CONNER. I will just tell you that the Secretary of Agriculture is closely involved in this effort, Senator Roberts, and I think that that is reflected in the time that he took to go to Kansas City this past May for the International Symposium an Agroterrorism. He was out there with you participating in that, and the Secretary is certainly in charge of this. We have an important team where I play a role in that as well, Jeremy Stump, and we have——

Senator ROBERTS. So you are sort of a troika?

Mr. CONNER. Well, it is a big task, Senator Roberts.

Senator ROBERTS. OK. Are you, the Secretary, and others receiving intelligence briefings that you need, and if so, how often do you receive these briefings?

Mr. CONNER. I believe we are. I think the briefings are available to us weekly, and if we need more than that, that is available as well. So I certainly have no complaints at this point.

Senator ROBERTS. Dr. McCarthy, your testimony today mentioned several of the divisions within the Department of Homeland Security that are involved with food and agricultural security. I am going to ask you the same question. Who is the head of the policy over there at DHS? Is it the Secretary? Deputy Secretary? Under Secretary You? Who do we talk to?

Ms. MCCARTHY. Yes, sir. Well, as you may have noticed in the Secretary's plan for reorganization, he has culled out specifically a policy office, which he is in the process of establishing right now. The Secretary, though, I can tell you personally takes the issue of agricultural security very seriously, and that is one of the major sectors of protection that we have deemed as a high-priority sector that needs to be protected.

Our information analysis, currently our information analysis an infrastructure protection division of the department is responsible for coordinating the agricultural security interface that we have with the public and private sectors through the government and sector coordinating councils. They coordinate all the dialog that we have. We in the Science and Technology Directorate support them and support the Secretary through our ability to do research and development and through our operations of the facilities, and obviously in the border protection, the inspection work is done in the borders, but we work very closely with our colleagues in NIAIP because they have the lead in communicating and coordinating the activities, not only inside of the Government, but with the public and private sectors.

Senator ROBERTS. I don't want to call an acronym. I want to call somebody. Is that you?

Ms. MCCARTHY. Sir, you would have to call—I would recommend you call the Secretary of Homeland Security.

Senator ROBERTS. He is a pretty busy fellow.

Back in 2002, I joined an exercise held by the department called Crimson Sky. That was sort of a misnomer because it followed the experience of Great Britain in regards to their problems with their livestock herds. They used that method in regards in incinerating the animals, which is probably the worst thing you could have done, as we found out.

There wasn't anybody else in town, so I played the role of President in this exercise, and it simulated the intentional introduction of foot and mouth disease in five different locations. By the way, the person who did that was from Iraq, at least in the exercise. The impact was incredible. In 6 days, if you do not detect the disease, that is when this or the effects of the disease first become obvious, and then it is too late. All of our exports stop. People in the cities discovered that their food doesn't come from grocery stores, and panic set in. The markets went crazy.

Basically, we had States calling out the National Guard. That is when we had the National Guard in the States, not over in Iraq and in Afghanistan and everywhere else, setting up all sorts of border situations so livestock in Texas couldn't go to Oklahoma; Oklahoma couldn't go to Kansas; Kansas couldn't go to Nebraska; etc., etc. It got pretty rough except everybody finally realized that all of the States were involved and we had to do something.

As President, I stopped the movement of all livestock. The Secretary of Commerce said you couldn't do that. So I fired him, and it felt very good. But it was absolute chaos and not only for 1 year and not only for livestock, but every crop. So if you talk about a real problem, that was a real problem.

So, Chuck, can you tell me are you still conducting these kind of exercises? You probably don't want to have me play President, but at any rate, are we doing the exercises that we need to do in conjunction with your compatriots up there on the panel, and has that impacted the way you do business?

Mr. CONNER. President Roberts——

Senator ROBERTS. No. That is Brownback. That is not me.

Go ahead.

Mr. CONNER. First of all, we did appreciate the role that you played in that. I think that was a very important simulation for us and we learned a great deal from that. I would just harken back to some of the experiences and, again, what we learned from that just in terms of the importance of quarantine and the role that that plays in an event like this, and I think others mentioned earlier the GAO report, this focus upon the vaccines. I think one of the problems you have with relying upon the vaccines to control situations like this is the fact that it does not do much for you in terms of international.

Senator ROBERTS. We had to terminate almost every herd in America. I mean that was the end result. It was an incredible experience when you really finally got down to the final answer to stop what was going on. We had to call out the National Guard and call out the military. Quite frankly, we ran out of ammunition. It was

a mess, and then you had PETA on television, and I can't describe the utter chaos that happened.

Mr. CONNER. I was there, if you recall, sir.

Senator ROBERTS. It was something that I had quite not expected all of the ramifications to happen. If we have that, we don't have the vaccines to do that.

Mr. CONNER. No.

Senator ROBERTS. We had to dig ditches miles long out of the water supply to get rid of the animals, and it was just absolutely devastating, which really gets back to the intelligence factor and are we getting enough intelligence.

Your prepared testimony discusses the Food and Agricultural Government Coordinating Council as the Department of Homeland Security, USDA, and HHS, along with Federal, State, and local officials, and I know that the DHS is the lead agency. How often do you meet?

Ms. MCCARTHY. Well, sir, there is actually a meeting with the full coordinating council next week.

Senator ROBERTS. Good.

Ms. MCCARTHY. And the subgroups meet regularly. There are lots of discussions that go out across the community both internal to the Federal Government and also across into the private sector.

Senator ROBERTS. Chuck, your prepared testimony talks about rapid test kits, and there is a lot of that in some legislation. I know Senator Cochran has been very interested in this. Can you tell me do we have the rapid test kits? I am talking about livestock here. Have they been distributed to the States? Are they located at the State labs? At the universities? At law enforcement, so on and so forth? Is there training? Where are we with that?

Mr. CONNER. Well, I think the rapid test kits are an important part of that, Senator Roberts, and I may need to supplement and get some APHIS people to give you the precise answer just in terms of their development, but let me just say the simulation, Crimson Sky situation that we had, underscored for us the importance of that rapid communication and knowing that if you get a positive hit somewhere in America, that information needs to be out there and distributed to our laboratory network very, very quickly so that we can get those containment measures in place before it does what happened in the simulation and gets too far away from us.

That has been a big part of what we have done with the additional resources that have been given us, is to improve this rapid communication and coordination among our labs so that we know almost instantaneously when something like this happens and then provide the appropriate notification to our colleagues at Homeland Security. FBI has been tasked to work with our I.G. so that they are involved in the event if it is a law enforcement-type issue.

Senator ROBERTS. That is after he reads the GAO report? Right?

Mr. CONNER. That is right.

Senator ROBERTS. All right. We have heard a lot lately. We even had a vote on the Senate floor regarding the distribution of homeland security funding, high threat versus lower threat areas, city versus rule. That is what it was about.

So, Dr. McCarthy, what priority is given to threats that are related to food and agriculture security when making these designations? Do you weigh in on that?

Ms. MCCARTHY. Yes, sir, we do, and I can tell you the risked-based approach that we are taking right now looks at the integration of threats, vulnerabilities, and consequences. We are concentrating heavily, though, on things that we think can have a catastrophic impact to the country, a national scale impact. So threats to the agriculture are things that we take very seriously. Actually, many of those wind up falling in the catastrophic category. Catastrophic doesn't include not only casualties to humans, but it includes potential economic impact or societal disruption.

So right now, the department has embarked on integrating a very solid rigorous risk-based approach to looking at those things that fall into the most catastrophic category, and those are the highest priority items that we are looking at, and there are all elements of the agricultural sector that are very important. Obviously, our big concern with foot and mouth disease reflects that.

Senator ROBERTS. I am glad to hear that.

On the Intelligence Committee, we are reminded daily in the national press that the al Qaeda is seriously looking at soft targets, and when we do the analyzing, first the collection and then the analyzing, we usually weigh intent and capability in trying to determine where best to focus our counterterrorism resources. Dr. McCarthy, do you believe we have enough information to determine the true threat?

You mentioned the Agriculture Intelligence Working Group. Can you tell me how often that group meets?

Ms. MCCARTHY. Sir, I would defer to my colleagues from the FBI to answer the issues specifically on intelligence.

Senator ROBERTS. OK.

Mr. LEWIS. It is a once-a-month meeting, sir.

Senator ROBERTS. All right. I will push for twice.

The last question that I have, and I am very happy that the Chairman has returned, tomorrow the Intelligence Committee is going to hold a confirmation hearing for Vice Admiral Redd to be the first confirmed Director of the National Counterterrorism Center, and this is going to be—already is—the primary entity in the U.S. Government responsible for both the strategic operational planning on counterterrorism and fund food security. Obviously, this is a very critical issue, as you have all have indicated.

Do you, and you meaning the USDA and FDA, currently have representatives assigned to the National Counterterrorism Center, and if so, are there plans to expand your agency's presence there?

Ms. MCCARTHY. Sir, yes, we do, and we work very closely with them on a regular basis, and we will more engaged with them, obviously, with the implementation of the WMD commission reports and the stand-up at DNI.

Senator ROBERTS. I thank you for your response.

And I have gone on for about 8 minutes, doing a soft shoe while you went to wherever you went, Mr. Chairman.

The CHAIRMAN. Would you like a blow by blow?

Senator ROBERTS. I think that is classified, sir, if you will remember.

The CHAIRMAN. Senator Dayton has left us.

Senator Cochran.

Senator COCHRAN. Mr. Chairman, thank you very much for organizing the hearing. I am here to thank the witnesses for their witness efforts to help us identify the threat that could be posed to our agricultural resources by bioterrorism and to emphasize the importance of research in figuring out ways to better protect the food security of our country.

I compliment all of you for your efforts to work across department jurisdictions and include the private sector as well as public sector agencies in this national effort. We appreciate the work that you are doing and we hope that through this hearing, we will learn more about how we can more helpful in supporting your efforts. If it means passing new authorizing legislation, then I am sure the chairman will call us together and put that challenge before the committee. If we are talking about appropriating funds that are necessary for new research facilities or for the empowerment of universities or other research capabilities in our country to do a better job in this effort, we would like to have the benefit of your advice and counsel in that way as well.

Mr. Chairman, I have some specific questions which I will simply ask that we submit for the record. One thing I will ask, though, and that is about the facilities at Plum Island. I know that the capabilities there are limited, and what is your assessment of this facility in terms of its capacity to meet our national needs in regards to these potential threats?

Ms. MCCARTHY. Thank you, sir, and we certainly are grateful for all the support that your committees have given us as well. As I stated earlier in my statements, we have assessed, obviously, the Plum Island Animal Disease Center, which is a facility whose lifetime, it has exceeded its useful lifetime as a facility. The Nation needs that critical capability. It needs the ability to have both the research, the diagnostics, the forensics, the training, and all the capabilities we need out 50 years in order to provide the Nation with a base to be responsive to the agricultural missions and the agriculture security mission that we are all in.

We have undertaken this year a feasibility study that will look at the requirements potentially for a new facility, merging those requirements with the requirements for mission responsibility from the DHS, from our colleagues at USDA, and from our colleagues at HHS, and we are building facility options from that set of requirements. So we take this very seriously and we take it as a national responsibility that the Nation needs to assess what it needs. We need to be able to provide the base that allows us to not only do the missions that we have done historically for the last 50 years, but also the missions that we have into the future.

Thank you.

Senator COCHRAN. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Salazar.

STATEMENT OF HON. KEN SALAZAR, A U.S. SENATOR FROM COLORADO

Senator SALAZAR. Thank you very much, Chairman Chambliss and, in his absence, Ranking Member Harkin. Thank you for hold-

ing this hearing on the issue of bioterrorism, because it is very much an important part of providing homeland security as well as making sure that we are protecting agricultural and rural America.

I recognize the huge contribution that agriculture makes to our economy in this country and in my own State of Colorado, and I know that without agriculture, much of what I call the forgotten America would go by the wayside. So I appreciate you putting a focus on the issue of agroterrorism.

And picking up on the comment from outgoing HHS Secretary Tommy Thompson, last year he said that we were extremely vulnerable to an agroterrorism attack, and in his statement about the threat, he said that it worried him, quote, every single night. I believe that he was right to worry.

I have an opening statement that is much longer, and I will submit that for the record, Mr. Chairman, if there is no objection, and I have a couple of questions that I would like to ask.

The CHAIRMAN. Your statement will be inserted without objection.

[The prepared statement of Senator Salazar can be found in the appendix on page 93.]

Senator SALAZAR. This is a question for Deputy Secretary Conner and for Dr. McCarthy, and that is a question on how we are coming together in the integration of DHS and the agriculture inspection services. I am trying to work my way through reviewing Secretary Chertoff's analysis on how the DHS organization is going and the recommendations that he has on how we ought to move forward with that. I recognize that whenever there was a major overhaul of government in the way that we have overhauled our government to deal with the challenge of homeland security, that there are very, very significant management challenges that we need face.

Here on this particular issue, my understanding is we had some 3200 inspector positions that we had at USDA, that those inspector positions have been moved over to DHS, and my question is how is that integration going with respect to what these inspectors are currently doing? A question that is part of that as well is I believe there was an authorization to hire an additional 500 inspectors, and I would like a report on where we are, on the status of the hiring of those inspectors, all coming down, basically, to the question do we have enough horsepower within DHS, men and women power, to be able to deal with the inspections at our ports and making sure that we have the readiness to be able to have those inspections done on a timely basis.

Ms. MCCARTHY. Yes, sir. Thank you very much.

I do hope that the reorganization plan that the Secretary presented last week helps clarify some things, because it should give you insight into the importance he is putting on very specific functional areas, less so on the management structure, how the department is managed, but more so on the fact that there is an attention and a high priority put on given functional areas, and one of those functional areas is border protection. So you will see the department align itself so that all of us who participate in things that have to do with border protection are working together in a more seamless fashion. So it doesn't matter whether it is somebody out of my office that is doing research and development or it is some-

body out of the intelligence unit or somebody out of Customs and Border Patrol or one of the other organizations. We will be working on teams that are focused on those functional areas.

The border protection integration took place within the Customs and Border Patrol part of the department, and in the new organization, that has stayed together. So each port is responsible for doing that integration, and it is coming along, and I will certainly take back for you the question for the record of where we are on the hiring of inspectors. I can tell you it has been a challenging job internally for DHS across the board to recruit and retain the qualified people that we need to do in many of the jobs, but I can tell you that we have taken the integration of border security as a topmost priority in the department, and the Secretary is very committed to pooling the resources not only from the traditional elements that came into the department initially, but merging additional capabilities against those mission responsibilities into the future.

Senator SALAZAR. If I may, Dr. McCarthy, a follow-up question in terms of the qualifications of the individuals that you are hiring or who are already on board to provide this kind of security, what kind of people are you looking for when you are trying to provide us the kind of border security that we want from the potential entry of some agroterrorist material that would come across our borders?

Ms. MCCARTHY. That is a very fair question, sir, and I will take back the question for the record on the specifics of the qualifications because I am not in that business, but I do know that they have held a very high standard of bringing people in and making sure that they were properly qualified and properly vetted for the positions that are involved, and I will be happy to respond to you in writing on the specifics of the qualifications for those inspectors, sir.

Senator SALAZAR. Just a follow-up, Mr. Conner, for you in terms of the USDA, to lose 3200 employees from this agency that has significant responsibility of making sure that we are protecting our consumers and our agricultural products, what kind of impact has that had to the historical pre-9–11 function within USDA?

Mr. CONNER. Well, it has not removed, if you will, Senator Salazar, our role in this process within this matrix. We continue to have jurisdiction on meat, poultry, and egg inspection. We have a significant role in that process for imported product, and that extends way beyond just simply at the point of entry into the United States. Our Food Safety and Inspection Service personnel are located in the foreign countries that are shipping the product to us before it even is destined for the U.S. There has to be a certification that the standards used in that production are equivalent or as strong as what they are in the U.S. We certify that equivalency and then audit at the point of processing in the foreign country.

So our role begins and, as well, our FSIS inspectors are present. Every container of these products that does enter the country, you know, is visually inspected to make sure that it shows no signs of tampering or anything at that point. I believe we have just added 26 new people at our ports of entry for that specific purpose.

So it has by no means eliminated our role, and we take this whole issue of equivalency and assurance of the meat, poultry, and egg product coming into this country quite seriously.

Ms. MCCARTHY. With respect, sir, if I might add one thing, I would encourage you to view Homeland Security as the steward of the homeland security mission. The fact that people move between one agency and another does not negate the fact that we have a national mission, and we are the stewards of a national mission, and our responsibility is to provide the Nation with the best capability and we work closely in partnership in a different way than this government has ever done with our partners in the Federal Government and also the State and local and private sector.

Mr. CONNER. If I could add, Senator Salazar, as well, actually, I believe in the legislation APHIS continues to set the policy for the employees that are under the jurisdiction of the Department of Homeland Security as well. So it is a strong cooperative relationship.

Senator SALAZAR. Thank you very much, and Mr. Chairman, just one concluding comment, and that is for those of us who come from rural States, and all us who sit on this committee I think have a special place in our heart for the rural communities. When I travel in my own State of Colorado and I go to the small communities and see the water tanks and the grain elevators and the potato warehouses, and I see those all over my native valley in the southern part of Colorado, I think it is just important for us to continue to look at the challenges that we face in homeland security, because it will be one of our major challenges for this twenty-first century and making sure that we are putting the right kind of resources and the right kind of attention out in those wide expanses of America.

So I think this hearing dealing with agroterrorism is particularly important in addressing at least a part of that issue. So I appreciate you holding this hearing very much.

The CHAIRMAN. Well, thank you, Senator, for your keen insight and your interest in this issue, and I think in Chairman's Cochran's Appropriations Committee, we appropriately dealt with the exact issue you are talking about, and that is where to put the resources. We simply can't forget rural America, and I think we did that in the homeland security bill last week.

Mr. Lewis, I want to kind of switch gears a little bit here. I know you testified before the Environment and Public Works Committee recently relative to ecoterrorism, and it is my recollection that over the last several years, we have had some incidents relative to ecoterrorism such as the physical destruction of some facilities in the western part of the country as well as some environmental groups who are really extremist-type groups who have done things such as putting blades in trees and not allowing our loggers out there to harvest trees and whatnot. I know that we have identified those groups. I assume we are continuing to monitor those folks. Have the number of these instances decreased in the last several years?

Mr. LEWIS. Ecoterrorism, sir, is the No. 1 priority of the domestic terrorism portion of our counterterrorism division. It is so because when you look at the last 10 years of activity from the

ecoterrorists, what they have run up in terms of numbers of incidents and dollars worth of destruction far exceeds anything else going on in this country in terms of domestic terrorism or domestic base.

With respect to this issue here today, we have seen very limited incidents, two I think in the last five or 6 years, not of any substance at all. They are much more oriented today toward things like housing developments, condominium developments, animal releases. SUVs, of all things, are on their scope. Because we characterize this back at headquarters as part of the domestic terrorist program, it sits on the JTTFs just like international terrorism matters do all across the country. It gets the same push in my every single field office as does international terrorism matters. I think that is important. It is on the radar all across the country.

Let me also tell you that up here, not only with the committee that you have mentioned, but the Senate Judiciary which I have testified before and most recently talked to staffers on, there is an interest, and I hope it continues, in amending legislation that I think we need to strengthen the toolbox that we use to take to these people. At the present time, I would consider the threat of agroterrorism from this side of the domestic terrorism problem to be minimal, based on what we know today. There is an awful lot going on in this country in this area from an investigation intelligence collection standpoint. I can't go into that, obviously, during this type of hearing, but we have a very good lens, I think, through which we look to see what is going on around the United States, what they are interested in, and what we see as their planned activity over the next several months.

The CHAIRMAN. Thank you.

Senator Roberts.

Senator ROBERTS. Dr. Brackett, we can't let you leave without a question. You mentioned in your testimony you have issued some specific guidelines, security guidelines, for the milk industry. I want to know what kind of response you have received from the industry and how well they are working with you to address your concern. I think there has been a little push-back on behalf of the producers.

Mr. BRACKETT. Well, Senator Roberts, actually we have been working very close with that particular industry at their request, I might add, to help them in several different ways, first of all, to the develop the guidance documents that you refer to, but also to share with them what we know about what their potential vulnerabilities might be and how they might take actions to avoid that. What we are hearing is that, for the most part, the industry, processing industry, is adopting much of the guidance. It is a process. It is in process. On the production side, I think that that is coming as well, and I do know that the associations that represent the dairy farmers are working with them to try to assist them in adopting some of the guidance documents that we provided on specific issues or specific parts of the guidance documents that are relevant to them.

Senator ROBERTS. So it is a good news situation?

Mr. BRACKETT. It is. There is always room for improvement, and we are working with the industries and with the associations to

help do that, but we have gotten good response from them, we think.

Senator ROBERTS. We talk about the livestock industry. If you really want to look at something where we talk about a soft target or whatever kind of target it is, you know, obviously milk would really be one that somebody could choose.

Chuck, I have one final question. A lot of people are concerned in the world health and agriculture arena that we have not received any complete information from China in regards to the true scope of the avian influenza outbreak in that country. So on the issue of this nature that could have a major consequence for both animal health and also human health, who is the lead agency? Is that you or the Department of Homeland Security? FBI? Or is it, again, a concerted effort, working closely together, of course?

Mr. CONNER. DHS would be the lead on this, working with us is my understanding, Senator Roberts.

Senator ROBERTS. Well, I have a suggestion. Back in 2002, you used some of your supplemental funding provided by Senator Cochran to establish what is called plant disease and animal health monitoring networks, and there are labs located at several universities, and I want to give you kudos, because it is my understanding that this network was used to quickly diagnose the discovery of the soybean rust last week in the U.S., and you alerted all the producers and they knew about it and they watched for it and they could treat it if, in fact, it happened. We really limited what could have been a real tough problem.

So my plea to you is take a look at these labs and these networks, more especially with something like this avian influenza, which according to some could be absolutely a very serious outbreak not only for this country, but for around the world.

And I thank you for your efforts in that regard and I thank the panel.

The CHAIRMAN. Let me also thank you for being here this morning and providing great insight and educating the members of the committee on this issue. Some of you have already been told that you have written questions that will be coming to you. There may be others as well. The record will be held open. I would ask that you get us your responses as quickly as possible. Again, thank you for your service to our country.

The CHAIRMAN. We will now move to our next panel. The next panel consists of Dr. John Sherwood, head of the Department of Plant Pathology at the University of Georgia in Athens; Dr. James A. Roth, Director of the Center for Food Security and Public Health at Iowa State University; Mr. James Lane, Ford County Undersheriff, Dodge City, Kansas; Mr. Mark J Cheviron, Corporate Vice President and Director of Corporate Security and Services at Archer Daniels Midland Company in Decatur, Illinois.

Mr. Roberts, I understand you have an introduction.

Senator ROBERTS. Mr. Chairman, we have heard a lot today from our Federal officials on this topic. As you know, one of the most important topics in this fight is that to deter and to detect one of prevention. An important player in this role would be our farmers, our ranchers, our agribusinesses, our veterinaries, and law enforcement at the local level.

We had a hearing before 9–11. The Intelligence Committee, the Armed Services Committee, and we have even had appropriators there. It was that important. We asked 41 agencies in the Federal Government who is in charge, are you ready in regards to international security and any kind of a terrorist attack. Of course, everybody said they were in charge and they were ready. The last person to testify was in charge of the Sheriffs Association, and he was from Arapaho County, Colorado, and he said, Well, boys, all these feds are here already, but it is going to take you 72 hours to get out to Arapaho County, and I just want to tell you one thing: Until you all get there, I am in charge.

So I think that is an important point to make, and I am proud to say that one of the most significant undertakings in this area has been undertaken by the Ford County, Kansas Sheriff's Office and the Kansas Bureau of Investigation and also Kansas State University, and they have been led by the Ford County undersheriff, James Lane.

The chairman just asked me, James, if we have an oversheriff as well as an undersheriff. You can speak to that.

James is with us today. His efforts have led to a substantive research report funded by the National Institute of Justice. This report has just been completed. I believe it includes many recommendations that will be a blueprint for other law enforcement folks around the country.

I am not going to steal James's thunder, so I will not go into all the details of their efforts, but I say that group has done just remarkable work. I am very proud of the effort of James and my home county, and, more importantly, I am very proud to say that he comes from Dodge City America, and I thank you, Mr. Chairman.

The CHAIRMAN. I'll tell you, Mr. Sheriff, any secrets you want to share with the committee about the Chairman of the Intelligence Committee while you are here will be welcomed.

Senator ROBERTS. James, you know that is all classified.

The CHAIRMAN. Gentlemen, thank you all very much for being here to dialog with us on this very critical issue, and, Dr. Sherwood, I won't go into a formal introduction of you, but obviously you probably noticed my hand over my heart when I said you were from the University of Georgia. We are very pleased to have you here, and we will start with you and come right down the row.

All of your statements will be submitted for the record, but we would appreciate and look forward to any opening comments you have. Dr. Sherwood.

STATEMENT OF JOHN SHERWOOD, PH.D., HEAD, DEPARTMENT OF PLANT PATHOLOGY, UNIVERSITY OF GEORGIA, ATHENS, GEORGIA

Mr. SHERWOOD. Thank you, Mr. Chairman. Thank you for inviting me here today to comment on biosecurity preparedness and efforts to address agroterrorism threats posed by plant diseases that impact the food, feed, and fiber of our nation.

My name is John L. Sherwood, and I am professor and head of the Department of Plant Pathology at the University of Georgia. I am also representing the American Phytopathological Society, or

APS, the premier organization of scientific leaders who work to keep plants heathy. Our member scientists are employed in universities, private industry, and agencies within the State and Federal Governments.

The U.S. has been blessed with vast tracks of productive land, but at times plant diseases have had significant economic and social impact. Today, plant pathologists are facing soybean rust and sudden oak death among other diseases that affect the vitality of our fields and forests. As with the diseases affecting animals and humans, new diseases of plants are regularly encountered here and abroad.

Positive steps to protect U.S. crops have been taken. Examples are the National Plant Diagnostic Network, the regulatory activities toward mitigating exotic pathogens by APHIS and State Departments of Agriculture. The EPA approval of Section 18 requests to provide expanded management tools to minimize the potential impact and damage caused by soybean rust, and the establishment and revitalization of crop biosecurity panels or centers within various government agencies.

Four key components of an effective approach to mitigate acts of crop terrorism and maintain safe and productive crop systems are strategic anticipation of potential threats, prevention of a bioterrorist attack, preparedness to respond to an attack, and coordination of these strategies. The foundation of security is identifying potential threats through strategic anticipation. Each year, plant pathologists in the public and private sector prepare to thwart diseases that may affect our nation's plant production systems. Fundamental to any aspect of plant biosecurity is understanding the biology of how plants get sick. This is why support of basic and applied research in a competitive grants process is essential for the security of our nation's feed, food, and fiber production system.

Prevention efforts must be directed toward securing the Nation against pathogens not yet in the U.S. Currently, much effort is spent on regulating pathogens that are widespread and endemic in the U.S. These pathogens pose no more threat in regard to biosecurity than they annually cause in naturally occurring epidemics. Such natural epidemics may be devastating in a given locale during any growing season, but extensive regulation of such endemic pathogens limits the ability of the scientific community to investigate and develop appropriate management strategies and results in squandered resources.

Effective communication between Federal agencies and scientific societies such as the APS will provide a solid foundation to prioritize these needs. As 100 percent prevention is impossible, we must be prepared for the introduction of pathogens. The recent establishment by the USDA CSREES of the National Plant Diagnostic Network that is dispersed among the land grant universities is working to establish coordinated efforts in APHIS, State Departments of Agriculture, and private seed companies to minimize the impact of plant diseases.

The elements for an effective national response plan and crop biosecurity are coming into place across State and Federal Governments. While the greatest consideration must be given to threats that directly impact human and animal health, we emphasize that

long-term human and animal health is dependant on sustainable agriculture production systems in the U.S.

As I indicated, there are many activities underway. What appears still to be lacking today as a scientist from outside the Government, and the biggest void to assuring success in all our efforts is effective communication, coordination, and strategic planning among the many entities that are charged to protecting plant health. Following 2 years of planning and solicitation of stakeholder input, in the fall of 2004 the APS released its proposal for the establishment of the National Center for Plant Biosecurity (NCPB) within the USDA as a Federal coordinating office staffed by Federal employees and administrated at the level of Office of the Secretary of Agriculture to coordinate efforts in crop biosecurity. The NCPB will function as a visionary strategic planning and coordinating entity, link Federal agencies and staff responsible for plant biosecurity, and not duplicate efforts underway.

This proposal has received wide support and endorsed by many scientific societies. The NCPB will provide a strong framework and leadership for anticipating, protecting, responding to, managing, and recovering from disease outbreaks as mandated in Presidential Directive HSPB–9.

In conclusion, the geographical expanse and economic importance of the U.S. agriculture enterprise creates a vulnerability for the intentional or unintentional introduction of plant pathogens that could directly affect crop yield and the viability of our crop production systems in our fragile rural economies. New investments in infrastructure and resources necessary to protect and maintain plant health will have significant social and economic impact both in the immediate future and for generations to come.

[The prepared statement of Mr. Sherwood can be found in the appendix on page 96.]

The CHAIRMAN. Dr. Roth.

STATEMENT OF JAMES A. ROTH, DVM, Ph.D, DIRECTOR, THE CENTER FOR FOOD SECURITY AND PUBLIC HEALTH, IOWA STATE UNIVERSITY, AMES, IOWA

Dr. ROTH. Thank you, Mr. Chairman and members of the committee, and thank you for holding this important hearing today and for the opportunity to testify before you.

I am the Director of the Center for Food Security and Public Health in the College of Veterinary Medicine at Iowa State University. Our center's mission is to increase national preparedness for accidental or intentional introduction of disease agents which threaten food security or public health. I would like to thank Senator Harkin for his vision in providing funding to establish the center so that we can work to carry out this important mission.

U.S. agriculture is highly vulnerable to the accidental or intentional introduction of foreign animal diseases. Many of the foreign animal diseases are zoonotic, meaning that they also infect people, and can cause serious public health problems. Agents against animals have been considered as a component of nearly every nation-sponsored offensive biowarfare program.

Significant progress has been made in recent years to better prepare U.S. agriculture and public health. The national animal I.D.

system is being developed. Expert working groups have been convened to establish research and vaccine development priorities. A number of States have organized or are working to organize animal emergency response teams. Veterinary diagnostic laboratories are networking to enhance national capacity and to better share information, and Congress has nearly completed funding for the modernization of the National Center for Animal Health in Ames, Iowa. These activities need to continue.

Despite the progress, the U.S. continues to have inadequate infrastructure for prevention, detection, response, and recovery from foreign animal and zoonotic diseases. The national academies are finalizing two reports that detail current needs for prevention, detection, and diagnosis of animal diseases and for veterinary research facilities and training. The significant challenges that I will focus the rest of my testimony on are the vulnerabilities and needs I consider the most important for protecting public health, animal health, and U.S. agriculture from disease threats. These priorities include the rapid development of vaccines and anti-virals for high-priority foreign and zoonotic diseases, correcting major deficiencies in the laboratory capacity for animal health research and disease diagnosis in the U.S., and strengthening the human resources needed to prevent, prepare for, respond to, and recover from a devastating foreign animal or zoonotic disease.

Homeland Security Presidential Directive–9 calls for the creation of a national veterinary stockpile. Rift Valley Fever, Nipah Virus, and avian influenza are especially significant threats because of their contagious nature and the fact that they can cause serious illness and death in humans. A relatively modest investment could result in the development and production of vaccines for these three diseases for the national veterinary stockpile. Animal vaccines can be developed for a small fraction of the cost of developing human vaccines and can be approved for use much quicker and with less risk than human vaccines.

Project Bioshield calls for $5.6 billion over a 10–year period for the development of vaccines and therapeutics for use in humans. A portion of that funding should be designated to develop vaccines and other preventatives for zoonotic diseases in animals. This will effectively reduce exposure of humans to these diseases, provide protection much sooner than is possible through the development of human vaccines, and reduce the need to vaccinate humans.

The second area I want to address is the deficiency in laboratory capacity for foreign animal and zoonotic disease defense. As has already been discussed today, the Plum Island Animal Disease Center does not have adequate capacity for the foreign animal disease research and diagnostic needs of the Nation. Planning should begin immediately for replacement of Plum Island animal disease center facilities, including biosafety level four facilities, and funding for new facilities should be appropriated as soon as soon as possible. I was very pleased to hear earlier today that that planning is beginning.

There are no biosafety level four facilities for livestock disease research in the U.S. I am currently coordinating a project to develop a vaccine for the Nipah Virus, a biosafely level four pathogen which causes serious illness and death in pigs and in people. Our collabo-

rators in Canada are using their biosafety level four facility to test the vaccine in pigs because the U.S. does not have facilities for this research in food animal species.

The third major deficiency is a shortage of personnel trained in veterinary medicine. There is a serious and acute shortage of veterinarians in rural agricultural areas, in Federal Government agencies, and in disciplines such as public health and food safety. There is also a critical shortage of DVM-Ph.D research scientists and teachers to train future scientists, especially in high-priority areas of veterinary infectious diseases. Funding of a National Veterinary Medical Services Act, which was signed by the President in 2003, but not funded, and the Veterinary Workforce Expansion Act of 2005 is critical to developing the human resources needed for foreign animal and zoonotic diseases defense.

Thank you for your commitment to protecting U.S. animal agriculture, and I will be happy to attempt to answer any questions.

[The prepared statement of Dr. Roth can be found in the appendix on page 101.]

Senator ROBERTS. Thank you.

STATEMENT OF JAMES LANE, FORD COUNTY UNDERSHERIFF, DODGE CITY, KANSAS

Mr. LANE. Senator Roberts, I am honored to provide testimony concerning the threats of agroterrorism and ongoing effort to protect American agriculture. Thank you for this opportunity and also thank you for your earlier comments.

My remarks today will be from the local law enforcement perspective. I will offer the committee an overview of the agroterrorism preparedness activities that are occurring at the local level in the State of Kansas. Further, I will speak briefly about our experiences, interaction, and initiatives with State and Federal officials, and I want to emphasize that we are never satisfied with our current level of preparedness as this is a continuing process.

The threat of agroterrorism is real. From recent events, we know there are forces that are seeking to harm America in any possible manner and that our agriculture is particularly vulnerable. We know that those who seek to harm us constantly change their tactics. We cannot overlook the threats to agriculture and our food supply.

In 2002, a group of local committed agriculture leaders volunteered to join our community's first responders to develop a comprehensive plan in response to threats of terrorism. This group of leaders recognized the importance of preventing an attack on our base. This coalition continues to assess any animal and public health issues that pose a threat to our community. The Ford County Sheriffs Office, Kansas Bureau of Investigation, and the National Agriculture Biosecurity Center at Kansas State recently completed a 2–year research project that was sponsored by the NIJ. Senator Roberts referred to this project a little earlier.

Previous writings and research identified the dire consequences of agroterrorism, but information related to law enforcement's roles and responsibilities were virtually non-existent. This project establishes a baseline for law enforcement to better understand the live-

stock industry and define its role in working together in the common cause of prevention. Further research is required to answer many of the unanswered questions related to this topic.

During the research project, several proactive initiatives were developed for law enforcement to specifically protect agriculture from criminal threats, including acts of terrorism. Local, State, and Federal agencies, including USDA and FBI, and industry participated in the research activities. The overall conclusion of this research project centered on the fact that terrorism, regardless of its former origin, is a local crime and preventive issues should be developed by local law enforcement in partnership with the livestock industry. Recently, a consortium of State and local animal health law enforcement emergency management and academia officials met in Kansas City to discuss strategies and prevention and emergency response issues related to agroterrorism. Representatives from South and North Dakota, Nebraska, Kansas, Oklahoma, Missouri, Colorado, and Iowa were present for this important planning session with the overall goal of sharing information and developing strategies that will work beyond State boundaries.

Our Agri-Guard program is the community policing strategy with the goal of bringing sheriffs and industry leaders together to encourage reporting of and education for front-line industry personnel in suspicious activity. Because of the interdependence of the industry, this program reaches across all facets of ag from pre-harvest to post-harvest stakeholders. Many States have shown interest in this concept developed by front-line industry personnel and local law enforcement.

You made mention of the ISA conference held in Kansas City, the International Symposium on Agroterrorism, and I think that offers a step toward the global initiative on preventing and responding to agroterrorism with that endeavor.

Across-the-country planning activities such as field exercises, other training, and communication is occurring. These food chain homeland security efforts must continue with a high degree of urgency. Further, because of the potential consequences associated with an interruption of the food supply, we cannot become complacent. Most importantly, all communities must understand that they are not immune from such an event.

Local first response agencies are far better equipped to respond to a WMD event because of funding from the Office of Domestic Preparedness. Agencies who just a few years ago could not offer their personnel protective equipment can now do so. In my perspective, the importance of intelligence information being thwarted from the ground up and the from the top down is critical. The local deputy sheriff responding to a report of suspicious activity thwarted by an alert industry professional is equally likely to identify and prevent agroterrorism as is the development of intelligence information at the national or international level. Lacking too, the industry must realize the importance of reporting such activity and being an equal partner in protecting itself.

In closing, I testified before a congressional field hearing at Abilene, Kansas in 2002. Significant process has been made since that hearing, but there are many threats and challenges that have yet to be addressed. In my opinion, the costs of response are far too

high and our focus must be on prevention. From the most simplistic initiatives of preventative policing to the most complex of disease surveillance and food safety technology , the need for prevention cannot be overstated. Federal grants and homeland security funding must be available to promote local preventative initiatives, research, and technology to protect against acts of agroterrorism. To eliminate confusion, miscommunication, and redundancy, it is essential that a national homeland security strategy addressing the threats of agroterrorism be developed and coordinated.

It has been an honor for me to represent local law enforcement in presenting this testimony. Thank you, and I will answer any questions.

[The prepared statement of Mr. Lane can be found in the appendix on page 105.]

Senator ROBERTS. Mark, it is ADM's time.

STATEMENT OF MARK J. CHEVIRON, CORPORATE VICE PRESIDENT AND DIRECTOR OF CORPORATE SECURITY AND SERVICES, ARCHERS DANIELS MIDLAND COMPANY, DECATUR, ILLINOIS

Mr. CHEVIRON. Good morning, Senator Roberts. I would like to thank you and the other honorable members of this committee for inviting me to address this issue.

I am Mark Cheviron, Corporate Vice President and Director of Corporate Security for the Archer Daniels Midland Company. Archer Daniels Midland, or ADM, is an integrated agricultural processor. We buy farm products, corn, soybeans, wheat, oats, cocoa, and produce food ingredients like edible vegetable oils, flour, animal feeds, and renewable fuels along with other industrial products. In order to produce and sell more than $36 billion worth of products each year, we rely on over 250 processing plants, more than 500 grain elevators, and a workforce of 26,000 employees worldwide.

Keeping our facilities secure and our people safe is my job. I have held this position for over 25 years. The threats I confront have changed over this period. While I used to worry primarily about threats of theft, fraud, vandalism, and workplace violence, I must now also be concerned about bioterrorism, and I am glad that you share that concern. America has made progress in hardening our defenses of traditional terrorist targets, military bases, government facilities, and commercial air travel. Only recently has our country turned its attention to better protecting crops, livestock, and the other products that flow from the farm communities.

As President Bush has said, "agriculture ranks among the most crucial of our Nation's industry, yet its reliability and productivity are often taken for granted." Protecting ADM from agroterrorism is my responsibility, but one that I cannot do alone. Business and government must work in partnership, and with each day, this partnership strengthens. We are grateful for the assistance we have received through the collaboration with organizations represented on today's first panel as well as with our local authorities. We are moving in the right direction, but more can be done.

Let me outline four areas in which I see room for improvement. No. 1, agroterrorism is an international problem, infinitely more comprehensive than any one company or industry. In order to be better prepared, the private sector needs better access to counterterrorism units of the Federal Government which has the means and the expertise to identify emerging threats. I may know the most effective way to mitigate these risks for ADM, but I can only address these if I know the risks. Federal counterterrorism experts can help the private sector understand potential threats which will guide our development of effective and efficient countermeasures based on those risks. We can enhance our overall level of preparedness by working together and maximizing our collective strengths.

Number two, a bioterrorist attack on our food supply can have a significant effect even when the amount of contaminant is small. The best response discovers and isolates a contaminant before it permeates and travels throughout the food chain. Today, the technology for detecting these threats is inadequate.

Number three, certain food security regulations which are knee-jerk, theoretical, uncoordinated, and counterproductive. Everybody agrees that agroterrorism is a complex problem, but regulatory approaches that proscribe across the board infrastructure changes or one size fits all procedural requirements are doomed to fail.

Number four, in order to win this war on terrorism, we need to enhance the exchange of information and expertise between the public and private sectors. This is harder than it sounds. We need to think through what restrictions are absolutely necessary to protect business and to protect sensitive government information and then devise a system that works for all interested parties. Information sharing is the key. It seems obvious, but in reality it means that timely and accurate information must flow both ways unimpeded and without hesitation.

Finally, we would welcome the designation of a single point of contact in the government for reporting suspicious activity. No time should be lost trying to determine who should be called when suspicions are raised.

Thank you, Mr. Chairman and honorable members of this committee, for allowing me to speak to you today. Agricultural processing is ADM's business. Ensuring the reliability and safety of our nation's food supply is everyone's business. We are proud to be your partner in the war against terrorism.

This concludes my testimony. I would be happy to answer any questions you may give me.

[The prepared statement of Mr. Cheviron can be found in the appendix on page 114.]

The CHAIRMAN. Gentlemen, thank you very much.

Dr. Sherwood, let me start with you. As you know, USDA is developing a national plant disease recovery system that will implement control measures and Develop resistant seed varieties; however, you propose the establishment of a national center for plant biosecurity in the secretary's office. Do you see the two proposals as complementary, or are they duplicative? Would it be more efficient to have one agency like ARS or APHIS handle all plant biosecurity rather than establish a new entity? And what does last

year's detection of soybean rust tell us in terms of our preparedness to respond to a sudden outbreak of plant disease?

Mr. SHERWOOD. Why don't we start with soybean rust, because that leads to a good reason why APS and myself support the establishment of a National Center for Plant Biosecurity. Last year at this time, we were working toward finding that person that Senator Roberts has repeatedly asked for, who do I call, and it was very difficult to find within USDA who was the person who we were supposed to call that was responsible for coordinating everything in regards to soybean rust.

I think currently, the present structure for the National Plant Disease Recovery Act being embedded within an agency is that essentially here you have another example of an add-on to an agency. Many of these agencies already have very directed missions. Certainly within APHIS, it is a regulatory mission. Within ARS, it is a research mission. Within the Department of Homeland Security, it deals with areas of security.

What I think is we need an office above the agencies, particularly within USDA, that would be able to coordinate these efforts, and so it would be that office one could call when there is potentially an outbreak of another plant disease such as soybean rust.

The CHAIRMAN. All right. Dr. Roth, you heard me talk or quiz the previous panel relative to the facilities in this country from an infrastructure standpoint that can respond quickly to an outbreak of any sort. In your testimony, you cite the need for biosafety level three and biosafety level four facilities as well as the need to replace the Plum Island Animal Disease Center. As you well know, the swift detection and diagnosis of disease is critical to preventing and/or limiting its spread, and this lack of research capacity greatly diminishes our efforts to detect, diagnose, and prevent disease outbreaks. Given the great exposure of these facilities, how would you prioritize our physical infrastructure needs in research and development?

Dr. ROTH. I would agree with the other panel members that replacing Plum Island is a very high priority. The new National Centers for Animal Health Facilities in Ames, Iowa will have extensive biosafety level three capabilities. It is not allowed to be used for certain foreign animal diseases that need to be done currently on Plum Island. We have no biosafety level four facilities that are adequate or any that will house large animals in this country, and I would put that as an extremely high priority. It takes a fair amount of time to design and build those facilities. So we need begin that very soon.

The CHAIRMAN. Senator Roberts.

Senator ROBERTS. Thank you again, Mr. Chairman.

Dr. Roth, I wish Senator Thomas could have been here to hear your testimony. I think it was very helpful, because I think I am struck on how you very clearly articulated the danger in regards to some animal diseases that also represent a threat to humans, and I thank you for your testimony. I don't wish you any luck with the Cyclones this year, but that is another subject entirely.

You talked about Plum Island and the resulting impact that it has on research and the diagnostic capabilities. The chairman had stressed this and the need to upgrade or replace this lab along with

the need for additional BL–4 labs throughout the country to conduct this kind of animal research. Do you have an estimate of how many BL–4 labs you think we need to in the U.S. to conduct this research?

Dr. ROTH. Currently, there are none that can house food animals, cattle.

Senator ROBERTS. I know that. That is why I am asking.

Dr. ROTH. I think one very good one would be sufficient. Canada does have in the Canadian Food Inspection Agency in Winnipeg a biosafety level four facility. They have one room that will hold food animals. That is the only one in this hemisphere that I am aware of.

Senator ROBERTS. Depending on the research being conducted and the public reaction to that, are there areas where these labs should not be constructed or are the security and control features such at that location that it is not an issue?

Dr. ROTH. The security and control features on the biosafety level three and four labs have to operate the way they are designed, and this is entirely possible. We have a number of biosafety level four labs with dangerous human pathogens in the middle of large cities, and we haven't had a serious accident that I am aware of.

Senator ROBERTS. But that was my point.

Dr. ROTH. Yes, and I agree. These labs are designed to operate safely and contain the pathagens. We have foot and mouth disease in the lab in Winnipeg in Canada just north of the border. As was pointed out earlier, the border is not that much of a protection from animal diseases.

Senator ROBERTS. I hope we can work this out.

James, your testimony has discussed the Agri-Guard program you established as part of the National Institute of Justice grant, and you described it or I described it as something of a neighborhood watch program for agriculture. You know what has happened over the past several years when I would go out to Dodge and talk to producers and they would tell me to hush about agroterrorism, and I have literally been amazed by the breadth and the depth of the participation in the program in Ford County from the farm level to the processors. How did you get that to work so fast and so well? Could you give us some practical examples? You keep talking about processors and private industry and local law enforcement or whatever, but, you know, I complained about it. You turned it around. How did you do that?

Mr. LANE. I don't know that I have the whole answer to that, but on the surface, I think I can tell you that our community enjoys a great working relationship between all levels of government, and I guess maybe what motivated us to work together was the fact that after the response is over and everybody that comes in to take care of it leaves, we have to live in that community. So I think what it does is it motivates the industry. It motivates us as first responders to reach out. One thing that I am constantly amazed at is that with the politics in the industry, that we can put people from different facets of the industry in the same room together and they don't brawl. They work toward the common good.

I think what we did, and this is not to pat myself on the back, but I think what we did was we kept going to the door and banging

on it and saying, you know, we want to work with you however we can, and I think that gave the industry the trust in the first response agencies that we did want to work for a common good. That is the only way I can answer that, sir.

Senator ROBERTS. Well, I think you have developed a model that could be used throughout the United States. I don't say that you are the only model, by any means, but what can we do to help you implement these programs on a national level? Although I guess that would be the Department of Justice and the previous panel. So I will let that go.

Your prepared testimony mentions the need for a national data base that could be connected to the Federal Terrorist Tracking System. So based on what you heard from our Federal officials today, do you think we are moving in the right direction in that regard?

Mr. LANE. I hope so. I think we have to stress the importance of intelligence information being forwarded from the ground level up and vice versa, but what is more important, I think, is that the people looking at that intelligence information understands what it means. Without a significant ag background or understanding of ag, that intelligence information may not mean anything and we may miss something.

Senator ROBERTS. I really appreciate that insight.

Mr. Cheviron, you said the private sector needs better access to the counterterrorism units of the Federal Government to which has the expertise to identify emerging threats, and you go on and say I know the most effective way to mitigate these risks for ADM, but I can only address those risks of which I am aware. Would you care to amplify on that in sync with the question I just asked James in regards to the fact are you aware?

Mr. CHEVIRON. Sir, we are aware of a lot of problems, but again, it is more on a parochial level as opposed to a Federal level. I think that the cooperation we have with the government now, the fact that we are meeting with so many different entities that are working so well together, is helping us understand emerging trends not only in terrorism, but in regular criminal activity. I think that is being shared much better now with the private sector.

Senator ROBERTS. I am glad to hear that. You, on No. 3, said certain food security regulations which are knee-jerk, theoretical, uncoordinated, counterproductive. You must be talking about the Congress. Everybody agrees that agroterrorism is a complex problem, but some will be required to spend needlessly to meet the mandates that neither efficiently nor effectively mitigate the real risks they face. Give me an example.

Mr. CHEVIRON. An example would be having a mandate to put a security officer on a dock in Ama, Louisiana to make sure that products going out of the country were safe and having a company pay for that.

Senator ROBERTS. Why is that unnecessary?

Mr. CHEVIRON. Well, I think our first priority should be what is coming into the country as opposed to what is going out.

Senator ROBERTS. I expected that you would say that. All right. So it is not so much what we are shipping out; it is the risk of what is coming in, and I don't think we have paid enough attention to

that, Mr. Chairman, and I know that you have been very concerned about it as well.

Finally, let me make a suggestion. In the intelligence community, we are moving away from the concept of information sharing. Information sharing basically states that somebody owns it and they will share with you, but they have to push that button. You have to pull it from them. You may not even be aware that it is there even though you have a mission or a problem that directly affects you. Information access, however, means that you all work together and if you have the same mission, the same objective, the same problem, the same challenge that Dr. Roth is talking about that you do have access. My only suggestion would be that we need to be talking not only in the intelligence community, but also in regards to private business, information access; and, James, that is what you have been talking about as well. So that is just a suggestion.

You say we have no easy avenue of recovery when this information is released inappropriately that causes hesitation. Senator Chambliss and I oversee 15 different intelligence agencies, not to mention the Department of Defense. That is like a wheel barrel with cats in regards to trying to get them to have access to information and see if we can't pull that out. The thought all of a sudden occurred to me that you have the same challenge in regards to private sector-wide with regards to your trade secrets or your information that is very special you. Do you have any comment?

Mr. CHEVIRON. No, sir. I think you have wrapped it up pretty well in what you just said. I think that there is some hesitation on private industry, not only with ADM, but the private sector in general, and that is because they want to protect proprietary information that they have developed and they don't want to really share that. They want to make sure that if they do share that information with the government, it is protected.

Senator ROBERTS. I appreciate that very much.

Thank you very, Mr. Chairman, and thank you for an excellent panel.

The CHAIRMAN. Mr. Cheviron, following up on that a little bit, when I put my intelligence hat on, information sharing is the top of my list. We talk a lot within the intelligence community about sharing information among Federal agencies, particularly law enforcement agencies, but what about in the private sector? Is the level of information sharing between the public sector and the private sector where it needs to be? Are we moving in the right direction or are you stone-walled there from the public side?

Mr. CHEVIRON. No, sir. I think we are moving in the right direction. I think that there have been improvements, of course, the real basis for sharing information is trust. It has to do with people knowing each other, knowing what they can share and what they can't, and I think that the Government and the private sector are working their way toward sharing information for the common good. I don't think it has to do anything like it used to be with turf, with protecting the information and knowing something someone else doesn't know. I have really seen a change in that in the last three or 4 years.

The CHAIRMAN. All right. Well, gentlemen, thank you very much for your participation in this hearing and being here today and helping educate the committee. The record is going to be left open for 5 days. There may be additional written questions that will be submitted to you, and I would ask that you get responses to those questions back to us as soon as possible.

Thank you very much, and this hearing is concluded.

[Whereupon, at 12:13 p.m., the committee was adjourned.]

APPENDIX

JULY 21, 2005

JULY 20, 2005

TESTIMONY OF THE HONORABLE CHARLES F. CONNER
UNITED STATES DEPARTMENT OF AGRICULTURE
BEFORE THE U.S. SENATE
COMMITTEE ON AGRICULTURE, NUTRITION & FORESTRY

Chairman Chambliss, Senator Harkin, Members of the Committee, thank you for holding this hearing today and for the opportunity to testify before you.

Today, the Committee raises a timely and important issue – food and agriculture security – that we at the U.S. Department of Agriculture (USDA) consider essential to our mission, which is to provide leadership on food, agriculture, natural resources, and related issues based on sound public policy, the best available science, and efficient management. In light of the recent media inquiries concerning the security of our food and agriculture systems, we appreciate the opportunity to provide you with an update on USDA's Homeland Security-related efforts. As you will see, the success of these efforts is due to and dependent upon the coordinated work of a broad range of Federal, State, local, and private sector partners.

Food and agriculture in the Context of Homeland Security

Agriculture exports this year should reach approximately $59 billion, making 2005 the third highest export sales year ever in our history – and significant to our balance of trade. Our nation's food and fiber system contributes approximately $1.24 trillion dollars, over 12 percent, to our gross domestic product and it employs about 17 percent of our entire workforce.

We face many challenges in protecting this important infrastructure. Our sector is particularly concerned about security because agribusiness is not constrained by political boundaries, and as we all know, diseases and pathogens do not respect state or national borders. The interconnected nature of the global food system is our strength, but it is also a disadvantage in the event of attack or natural disease outbreak. Additionally, one of the agricultural sector's greatest contributions to the quality of life is the fact that

products flow quickly through interstate commerce – one of our greatest assets is also one of our greatest concerns because intentionally or unintentionally contaminated products could quickly spread a pest, disease or other agent.

Since September 11, 2001, USDA has made great strides to expand our mission to include security. What has not changed is our conviction that the threat to agriculture is a very real threat. The Department has been working closely with its Federal, State, and local government partners, as well as with industry stakeholders to address these concerns and others via a sector-wide strategy based on White House guidance.

We are relying upon guidance provided in Homeland Security Presidential Directive (HSPD)-7: *Critical Infrastructure Identification, Prioritization, and Protection* and in HSPD-9: *Defense of U.S. Agriculture and Food* to strengthen our preparedness for intentional acts of terrorism against food and agriculture and for enhancements to current programs designed to prevent or control the unintentional introduction of agents, pests, and diseases that could harm our sector.

HSPD-7: Critical Infrastructure Identification, Prioritization, and Protection

USDA has worked in coordination with the Department of Homeland Security (DHS) and our partners at the Department of Health and Human Services' Food and Drug Administration (DHHS/FDA) to ensure that we develop a coordinated approach towards implementing HSPD-7 for the food and agriculture sector. Central to this directive, are the requirements for the government to collaborate with the private sector for infrastructure protection purposes and to create an overarching framework and unique sector plans for protecting key assets and resources.

Since August 2003, USDA, DHS, and DHHS/FDA have worked with Federal, State, local, and private sector participants to establish a formal entity for sharing sensitive information, new policies, best

practices and vulnerability assessments on a regular basis to help ensure the protection of the U.S. Food and Agriculture Sector. The government entity, the Food and Agriculture Government Coordinating Council (GCC), is led jointly by DHS, USDA, and DHHS, and includes Federal, State, and local officials. The private sector entity, the Food and Agriculture Sector Coordinating Council (SCC), is comprised of 2 leadership officials and an alternate from each of 7 sub-councils representing the farm-to-table continuum. The Councils regularly hold individual and joint calls to discuss issues of mutual interest such as sector vulnerability assessments and federal research and development plans. As a result of the joint sessions, the Councils create working groups to address specific issues and report recommendations.

HSPD-9: Defense of U.S. Agriculture and Food

To help safeguard our sector from intentional threats, USDA received $328 million from the 2002 Department of Defense and Emergency Supplemental Appropriations for Recovery from and Response to Terrorist Attacks on the United States Act to fund homeland security-related programs and initiatives. In addition, the Department through the Administration's FY 06' Food and Agriculture Defense Initiative budget submission has requested $376 million to assist in implementing HSPD-9.

HSPD-9 states that a national policy must include programs addressing:

- Awareness & Warning;
- Vulnerability Assessments;
- Mitigation Strategies;
- Response Planning & Recovery;
- Outreach & Professional Development;
- Research & Development; and
- Coordinated Budgets.

Awareness and Warning

One of USDA's key goals is to expand our surveillance and monitoring systems to provide early detection and tracing of diseases and outbreaks. In addition to expanding our systems, it is important to integrate them at a higher level – to permit us to notice aberrations across mission areas and across sectors. Intelligence is also essential to awareness and warning so that we are knowledgeable of our enemy's intent and capabilities. We use intelligence to prioritize many surveillance and monitoring activities. Therefore, USDA is forging new relationships to improve upon our preparedness and early warning capabilities.

Animal Health Surveillance Efforts

Animal and Plant Health Inspection Service (APHIS) is enhancing its animal health surveillance systems by collaborating with its counterparts in the Canadian and Mexican governments. One means of collaboration is via participation on the North American Animal Health Committee, which includes experts from the U.S., Canada, and Mexico considering surveillance methods for detecting a foreign animal disease (FAD) and how to demonstrate that the FAD has been controlled. The experts are preparing a gap analysis describing what we must do in order to return to trading status sooner.

Offshore Pest Surveillance

APHIS currently maintains the Offshore Pest Information System (OPIS). OPIS is a structured, risk-focused process designed to collect, synthesize/analyze, and communicate relevant offshore agricultural pest and disease information. APHIS plant and animal health specialists located overseas monitor and track agricultural pest and disease situations for OPIS reporting. APHIS uses this information to prevent against or prepare for the possible introduction of pests or diseases into the country.

Food Testing for Threat Agents

Early warning of food contamination can save lives. Therefore, USDA's Food Safety and Inspection Service (FSIS) is also focusing upon surveillance to ensure awareness of contamination or an outbreak related to meat, poultry, or egg products as soon as possible. FSIS has expanded its longstanding regulatory sampling program to also test for harmful chemical, biological, and physical hazards in meat, poultry and in egg products. The proportion of samples tested for threat agents is dependent upon the DHS threat condition.

Consumer Complaint Monitoring System

FSIS Consumer Complaint Monitoring System is a national system to monitor and track food-related consumer complaints. This is a real-time, early-warning system of a potential attack on our food supply. This system is an example of building upon existing safety tools to also include security goals.

Electronic Commodity Ordering System (ECOS) expansion

Similarly, the Food and Nutrition Service's (FNS) program, ECOS, also builds upon an existing program to include new facets to enhance safety or security. Adapting the ECOS to include a commodity food safety complaint component is the first step in implementing a rapid alert and notification system to reach State and local commodity recipients with up-to-the-minute food safety information. This change will allow local schools to report defective foods in a timely manner and will enable FNS to see trends in complaints and 'connect the dots' should an intentional contamination appear in different places at the same time.

Laboratory Networks

Detecting pests, disease outbreaks or contamination quickly enable us to determine the origin, respond, and mobilize sooner, which reduces the impact of an event. Therefore, our laboratories, are important surveillance tools. To enhance our detection ability and our response capabilities, we have established

national networks of federal and state laboratories with the capacity to test animal, plant, and food samples for threat agents in the event of a terrorist attack. USDA has also joined a consortium of laboratory networks including animal, plant, food, public health, defense, and environmental interests.

USDA hosts 3 laboratory networks – the National Animal Health Laboratory Network (NAHLN), the National Plant Diagnostic Network (NPDN) and the Food Emergency Response Network (FERN). Note that USDA co-hosts FERN with DHHS/FDA. These networks leverage Federal and State resources to enhance detection of and enable a rapid and sufficient response to food, animal and plant health emergencies. Their main goals are to improve information sharing, surge capacity, and coordinated resource allocation.

To enhance surveillance capabilities, laboratory networks from a variety of Federal Departments have agreed to work cooperatively in an Integrated Consortium of Laboratory Networks (ICLN.) All have signed onto a Memorandum of Understanding to communicate and cooperate by sharing capabilities, policies, procedures, and approaches for handling laboratory analysis during national emergencies. The consortium also seeks to reduce redundancies among laboratories, identify holes in laboratory capabilities, and to seek solutions to managing these identified issues in the future.

Coordination with the Intelligence Community and Law Enforcement

USDA is expanding its partnerships to include nontraditional partners such as intelligence community members and law enforcement agencies. One way to develop strong relationships is to work side-by-side with these entities. USDA has a senior intelligence advisor assigned to USDA's Homeland Security staff who works primarily on information sharing between the intelligence community and USDA, bolstering that vital connection. In addition, FSIS is providing staff to the National Counter-Terrorism Center.

Vulnerability Assessments

Vulnerability assessments play a key role in helping us to determine and implement the most effective countermeasures to prevent a terrorist attack on our sector.

Interagency Site Assistance Visits

USDA is partnering with the FBI, DHHS/FDA, and DHS to visit a variety of sites within the sector for the purposes of validating previously conducted vulnerability assessments, initiating new assessments, and fostering improved relations among industry, local law enforcement, FBI officials, and USDA, and DHHS/FDA field staff. Findings will also be used to consider mitigation strategies and to populate DHS databases. To ensure appropriate government and industry participation, the effort will be synchronized via the Sector Coordinating Councils.

Additionally, FSIS has completed seven vulnerability assessments for selected domestic and imported food products. And APHIS has completed four assessments for selected agricultural production industries. Both agencies have provided technical expertise concerning the application of the CARVER + Shock assessment tool, threat scenarios, as well as general assistance, to industries conducting their own assessments. These assessments, at the request of industry, have resulted in industry learning more about their vulnerabilities and they provided a forum to consider mitigation strategies. To date, USDA agencies have assisted private sector entities including National Pork Producers Board, the Texas Cattle Feeders Association, and Kraft foods. USDA plans to formalize our agencies' outreach and assistance via the Interagency Site Assistance Visits mentioned previously.

Mitigation Strategies

Early awareness enables a more effective mitigation strategy. Therefore, USDA has the goals of developing animal tracking systems, and expanding screening and inspection procedures, so that we may quickly respond to an attack or naturally occurring incident.

National Animal Identification System (NAIS)

The implementation of a national animal identification and tracking system is a top priority for USDA. Along with our state and industry partners, we're moving forward to implement such a system. NAIS will enhance the speed and efficiency of disease trace backs by standardizing animal movement recordkeeping and using newer technologies. Upon full NAIS implementation, we aim to reach our goal of tracing the movements of all exposed or infected animals entered in the NAIS within 48 hours of a disease diagnosis.

Targeted Screening and Inspection of Imported Food

FSIS works collaboratively with the importing establishment's government and uses a three-part process to verify that other countries' regulatory systems for meat, poultry and egg products are equivalent to that of the U.S. and that products entering the U.S. are safe and wholesome. Each meat, poultry and egg product shipment enters the country under the authority of U.S. Customs and APHIS and is transferred to FSIS where inspectors visually inspect every shipment as well as its accompanying documentation. To aid in security, FSIS established the role of the Import Surveillance Liaison Inspector in 2002. FSIS has hired 22 import surveillance liaison officers who conduct a broad range of surveillance activities at import facilities and serve as liaisons to improve coordination with other agencies concerned with the safety of imported food products.

Minimizing the Impact of Soybean Rust on the Agriculture Industry

Under APHIS' *Strategic Plan to Minimize the Impact of the Introduction and Establishment of Soybean Rust on Soybean Production in the United States*, published in November 2004, recovery from the introduction of soybean rust (SBR) introduction will involve a coordinated effort of Federal and State agencies, industry, growers, and crop consultants. The components of recovery include technical support and outreach. The USDA SBR website provides a one-stop source for SBR - including an early warning

system designed to provide timely SBR finds and recommendation for control. APHIS led the effort to design a coordinated framework for SBR surveillance and forecasting and is developing a transitional document to transfer leadership of these soybean rust activities to the States.

Preventing Animal and Plant Pests and Diseases from Entering the U.S.

USDA remains committed to maintaining a strong relationship with DHS and working cooperatively to ensure the continued success of agricultural inspection operations at all U.S. ports of entry. For example, APHIS is working with DHS/CBP to establish a quality assurance program for agricultural inspections. This program will ensure the quality and thoroughness of inspections and further facilitate communications.

USDA and DHS are also cooperating on new technologies to enhance border inspection efforts, including development of an automated inspection system to screen manifests electronically and target high-risk cargo; remote digital imaging to quickly identify pests on imported items; and a nationwide database of regulation violators.

Response Planning and Recovery

In the event of an attack or unintentional contamination or outbreak, it is important that we all know our respective roles and responsibilities. The National Response Plan, recently issued by DHS, is integral to ensuring coordinated incident responses.

National Response Plan (NRP) Implementation

USDA staff offices are identifying and preparing revisions to existing regulations, policies and guidance to assure compliance with the NRP. USDA has developed and is delivering NRP training courses for USDA employees and stakeholders.

Under a cooperative agreement, USDA, DHS, DHHS/FDA, and the National Association of State Departments of Agriculture formed a working group to develop the Food and Agriculture Annex to NRP and the interagency Food and Agriculture Response Plan that will implement the annex. To date, the working group has finalized the annex, the template for the Plan, and is in the process of populating the Plan.

We're also sharpening USDA's readiness for the Incident Command System. This is a part of a command approach that gives Federal, State and local governments a unified strategy for working together to prepare for, respond to, and recover from domestic incidents.

National Plant Disease Recovery System (NPDRS)

USDA is working with Federal agencies, State and local governments, and the private sector to develop a system, the NPDRS, capable of responding to a high consequence plant disease. USDA Agricultural Research Service (ARS) has assumed leadership of this effort and initiated a roadmap for implementation. The National Plant Disease Recovery System will implement sufficient control measures and develop resistant seed varieties for economically important crops.

National Veterinary Stockpile (NVS)

APHIS administers the NVS for specific, high threat foreign animal diseases. It is capable of maintaining vaccines for use in the U.S. in the event of a significant foreign animal disease outbreak. APHIS will use the NVS to consider and obtain "ready-to-use" vaccine products. The goal is for NVS to become one component of an overall response planning and recovery effort to provide the best possible protection against an attack on our food and agriculture system.

APHIS has awarded a five-year contract to Fort Dodge Animal Health to develop an avian influenza (AI) vaccine antigen bank for poultry that will house enough frozen antigen to produce up to 10 million doses of vaccine for a variety of AI subtypes. In the event of a high pathogenicity AI (HPAI) outbreak, the

frozen antigen would be used to prepare the vaccine for possible use in poultry in order to manage the disease.

Outreach & Professional Development

APHIS is educating its own staff, producers and veterinarians on livestock biosecurity so that they can be prepared to identify and to diagnose infectious diseases. APHIS worked with DHS' Office for Domestic Preparedness to develop an Agriculture Emergency Response Training (AgERT) course in Anniston, Alabama. AgERT prepares APHIS employees to serve as emergency responders. The course is targeted to responding to emergencies in an agricultural setting, but its instruction covers the use of personal protective equipment in all manner of emergencies, including chemical, radiological, and biological emergencies.

Because individual training is not always possible, USDA relies upon CD and web-based training. They are particularly effective mechanisms when the target audiences are widespread and in rural areas where traveling to a training site is difficult.

FSIS is also working with industry organizations to actively seek out opportunities to encourage adoption of food security activities, especially the use of vulnerability assessments and model food security plans. To educate industry on actions that they may take to increase security at their facility or within the system, FSIS issued three sets of voluntary guidance documents:

- *Food Security Guidelines for Food Processors*, targets slaughter and processing plants. It helps establishments identify ways to strengthen their protection against intentional contamination.
- *Safety and Security Guidelines for the Transportation and Distribution of Meat, Poultry and Egg Products*. This publication is designed to help facilities and shippers that process or transport meat, poultry and egg products identify potential vulnerabilities in their own operations and address them.

- *Food Safety and Food Security: What Consumers Need to Know*, outlines practical information for consumers about safe food handling practices, foodborne illness, product recalls, keeping foods safe during an emergency and reporting suspected instances of food tampering.

Using the guidance materials, FSIS prepared a checklist for industry to use to see if they are effectively implementing the voluntary security guidance. In addition, to encourage this kind of voluntary action in protecting the food supply against all threats, FSIS has released four model food security plans for the following four types of facilities: egg processing facilities, meat and poultry processing facilities, slaughterhouses, and import facilities. These plans are based upon the vulnerability assessments and checklists and are geared to serve as models to assist industry in developing their own facility-specific food security plans. To help industry adopt the plans, USDA will reach out to all target establishments with a specific emphasis on smaller companies that might not have the resources to develop their own independent security plans. As part of its outreach program, FSIS is providing training tailored to small and very small plants to encourage industry to adopt food security plans. While these guidelines are voluntary, FSIS strongly urges all establishments operating under Federal and State inspection programs to incorporate these security procedures.

Agriculture Transportation Security Guidance

USDA and the American Trucking Association developed a voluntary security guidebook and risk assessment tool for use by truck company owners and drivers to enhance security from external threats, including terrorism, and to protect trucking facilities and vehicles.

Externships and Fellowships

The field of food and agriculture security is relatively new, and therefore has few experts. Ensuring a competent and robust workforce of the future is important to the security of the sector in the long term. USDA has a number of initiatives to encourage study in this field. APHIS is collaborating with

Veterinary Schools to establish externship programs between senior veterinary students and various Units within the Agency's Veterinary Services program. In addition, FSIS currently employs several post-graduate fellows who are engaged full-time in bioterrorism and vulnerability assessment activities.

Research and Development

USDA is constructing a world-class animal disease bio-containment facility for research and diagnostics in Ames, Iowa that will house the Centers for Animal Health which are the National Animal Disease Center of ARS, the National Veterinary Services Laboratory of APHIS and the Center for Veterinary Biologics of APHIS.

USDA is developing a comprehensive suite of rapid diagnostic tests to detect and identify pathogens within hours that pose the greatest threat to U.S. livestock. Rapid detection tests for Foot and Mouth disease, Classical Swine Fever, Avian Influenza, and Newcastle disease have been transferred to APHIS for use in the National Animal Health Laboratory Network.

USDA Research -Crop Disease Detection and Food Defense

ARS scientists working on crop diseases have developed rapid tests for plant threat agents. These highly sensitive and accurate tests provide diagnosticians with an accurate means to detect pathogens as part of a national surveillance system. The rapid test for soybean rust (SBR) played an important role in the detection of SBR, in following its spread, and in the application of technology to reduce the impact of SBR.

Future ARS research will ensure that disease resistant varieties of plants and crops are continuously developed and made available to farmers and producers, will develop real-time, field deployable surveillance and detection methodologies and coordinate the validation process and will determine how the environment affects the establishment, spread and persistence of a threat in an agricultural context.

ARS has worked closely with USDA agencies and other Departments to address research and development needs resulting from vulnerability assessment findings. Methods were successfully developed to detect *B. anthracis* in milk on the farm, during transport/handling and at the processing plant to assure biosecurity.

Modeling and Mapping Development

The Economic Research Service (ERS) developed the Geo-Spatial Economic Analysis (GSEA) System to serve as a platform for collaborative analysis of the economic consequences of natural and man-made threats to food and agricultural industries. The GSEA system can be used to examine the economic impact of events that disrupt the production, processing, distribution or consumption of food and agricultural products. The key to this system is the ability to leverage existing expertise and analytical capacity at ERS by identifying and filling data gaps, integrating the results of dissimilar economic analyses and developing interfaces with plant and animal epidemiology models

Coordinated Budget

HSPD-9 directed a coordinated budget submission by USDA and DHHS/FDA to ensure collaboration during program and budget planning. USDA coordinated with DHHS/FDA to submit the Food and Agriculture Defense Initiative (FADI) for fiscal years 2005 and 2006.

Closing

Mr. Chairman, thank you once again for holding this important hearing. The Department looks forward to working with the Committee in continuing to develop programs and initiatives to help enhance our nation's agriculture and food systems. I would now be pleased to take any questions you or other members may have.

Statement for the Record

Dr. Maureen I. McCarthy
Director, Office of Research & Development
Science and Technology Directorate
Department of Homeland Security

Before the U.S. Senate
Committee on Agriculture, Nutrition, and Forestry

July 20, 2005

INTRODUCTION

Good morning, Chairman Chambliss, Senator Harkin, and distinguished members of the Committee. I am pleased to appear before you today to discuss the progress the Science and Technology Directorate of the Department of Homeland Security, in close cooperation with our sector-specific agency partners, is making in the nation's efforts to prevent, protect against, respond to, and recover from acts of bioterrorism against the critical infrastructures for agriculture and food.

The Department of Homeland Security's (DHS) responsibilities for agrodefense are defined in several public laws and Homeland Security Presidential Directives (HSPD), including:

- The Homeland Security Act of 2002, which includes provisions for:
  - Protection of the nation's critical infrastructures;
  - Development of biological countermeasures; and
  - Transfer of the Plum Island Animal Disease Center from the U.S. Department of Agriculture (USDA) to DHS.
- Congressional appropriations for:
  - Fiscal Years 2004, 2005, and 2006 (proposed).
- Homeland Security Presidential Directives, including those for:
  - "Management of Domestic Incidents" (HSPD-5);
  - "Critical Infrastructure Identification, Prioritization, and Protection" (HSPD-7);
  - "National Preparedness" (HSPD-8);
  - "Defense of United States Agriculture and Food" (HSPD-9); and
  - "Biodefense for the 21st Century" (HSPD-10).

INTERAGENCY COORDINATION

DHS is responsible for coordinating the overall national efforts to enhance the protection of the critical infrastructure and key resources of the U.S., including plant and animal agriculture and food; for coordinating the development of an interagency National Response Plan (NRP) and National Incident Management System (NIMS); and for coordination of Federal resources utilized in response to or recovery from terrorist attacks, major disasters, or other emergencies. Other Federal departments and agencies have specific roles and responsibilities that are outlined in documents such as Critical Infrastructure Identification, Prioritization, and Protection (HSPD-7), Defense of United States Agriculture and Food (HSPD-9), and Biodefense for the 21st Century (HSPD-10), and these are summarized briefly below.

In particular, HSPD-7 designates sector-specific agencies to address the unique characteristics and operating models for each sector. The U.S. Department of Agriculture

(USDA) is responsible for agriculture and certain foods (meat, poultry, and egg products); the Department of Health and Human Services (HHS) is responsible for public health, healthcare, and foods other than meat, poultry, and egg products; and the Environmental Protection Agency (EPA) is responsible for drinking water and water treatment systems. The Department of Justice (DOJ), while not designated as a sector-specific agency, has the responsibility for reducing terrorist threats and investigating and prosecuting actual or attempted terrorist attacks.

Additionally, the Department of State (DOS) is the designated lead agency for the coordination of international activities related to the prevention, preparation, response, and recovery from a domestic incident; DHS coordinates with the USDA, HHS, EPA, DOJ, and other Federal agencies to ensure that the combined Federal, State, local and tribal response capabilities are adequate to respond both quickly and effectively to a terrorist attack, major disease outbreak, or other disaster affecting the national agriculture or food infrastructures; and the Technical Support Working Group (TSWG) has and continues to play a unique integrative role as an interagency rapid prototyping program for combating terrorism technologies. TSWG operates under the policy oversight of the Department of State and under the management and technical oversight of the Department of Defense, and members include DHS, USDA, the Food and Drug Administration, DOJ, DOS, the Department of Transportation, EPA, and the Intelligence Community, including identifying, validating, and prioritizing interagency requirements to combat terrorism and deliver technology solutions for detection, protection, decontamination, mitigation, containment, and disposal.

DHS RESPONSIBILITY FOR AGRODEFENSE WITHIN MULITPLE ORGANIZATIONAL ELEMENTS

Before specifically addressing the activities of DHS Science and Technology (S&T) Directorate, it is important to note that several other DHS organizational elements have important roles and responsibilities for agrodefense.

The Information Analysis and Infrastructure Protection (IAIP) Directorate has the lead for critical infrastructure protection (including agriculture and food); the S&T Directorate supports IAIP in this role. IAIP coordinates the National Infrastructure Protection Plan (NIPP) which includes shielding critical components of the nation's infrastructure and development of pre-event mitigation strategies. IAIP has the lead DHS role in outreach to the private sector through the interfaces provided by the Food and Agriculture Sector Coordinating Council and the Government Coordinating Council. IAIP also provides DHS intelligence assessment for the agriculture and food sectors. In addition, IAIP establishes and facilitates public-private partnerships with industry for information sharing, development and deployment of infrastructure "shields" and mitigation strategies and to reduce the overall risk to the infrastructure form terrorism.

The Emergency Preparedness and Response Directorate coordinates the National Response Plan (NRP) and the National Incident Management System (NIMS). The NRP

includes Emergency Support Functions (ESFs) to provide Federal resources during a response, including those for agriculture and natural resources (ESF-11, USDA lead) and health and medical services (ESF-8, HHS lead); and Support Annexes to ensure efficient and effective incident management, including those for science and technology (DHS S&T Directorate lead).

The Border and Transportation Security Directorate has a major role in mitigation strategies for agrodefense, including border and cargo inspections of agriculture and food products entering the U.S.

S&T DIRECTORATE RESPONSIBILITY FOR AGRODEFENSE

Within the S&T Directorate, agrodefense is a key thrust in the Biological Countermeasures Portfolio, whose mission is to provide the understanding, technologies, and systems needed to protect against biological attacks on the nation's population, agriculture, or infrastructure. Within this mission, the S&T Directorate has the lead role for overall coordination, intelligence support, early detection and attack analysis, and bioforensics analysis and works closely with its sector-specific agency partners on agrodefense (USDA, HHS) and decontamination (EPA).

Our initial emphasis is on high consequence threats, as exemplified by an initial set of reference scenarios, including those for contagious and non-contagious aerosols, foreign animal disease (e.g., foot-and-mouth disease (FMD)), bulk food contamination, and crop defense (e.g., soybean rust). For each scenario, decision support tools guide our investments and enhance coordination, including:

- End-to-end systems studies to develop requirements and guide research and development investments;
- Epidemiological and economic models (e.g., for FMD), to explore intervention strategies and options for detection and response; and
- Crisis action planning and tabletop exercises to clarify agency roles and responsibilities.

Such exercises for FMD will be especially important, because internal DHS roles and responsibilities map to multiple DHS organizational elements (see above), and this will be the first time they have been exercised since the Department was created. In addition, new national frameworks for coordination (NIPP, NRP, NIMS) and tools, such as the FMD model and dynamic simulation of critical infrastructure, are now available. We plan to exercise internal DHS roles in an FMD scenario during FY 2005 and to exercise interagency roles of DHS with our sector-specific agency partners during FY 2006.

Biosurveillance

A major new interagency initiative is the National Biosurveillance Integration System (NBIS), whose goal is to enhance early detection and characterization, provide situational awareness to guide response, and share information among partners.

NBIS will provide for the integration of information provided by Federal agencies for health surveillance (human, animal, and plant), environmental monitoring (air, agriculture, food, and water), and intelligence and threat information.

The S&T Directorate led and funded the conceptual design effort for NBIS during FY 2004, and DHS IAIP is leading and funding the implementation process.

THE S&T DIRECTORATE'S ROLE IN AGRODEFENSE RESEARCH AND DEVELOPMENT

The S&T Directorate has a significant role in the coordination of research and development under HSPD-9, including:

- Acceleration and expansion of the development of current and new veterinary countermeasures;
- Developing with USDA a plan to provide facilities for research and diagnostic capabilities for foreign animal and zoonotic diseases; and
- Establishing new university centers of excellence for agriculture and food security.

In 2003, the S&T Directorate and USDA (Agricultural Research Service [ARS], and Animal and Plant Health Inspection Service [APHIS]) began developing a joint strategy for foreign animal disease. One of the first goals of the strategy is to develop veterinary countermeasures for foot and mouth disease. Following the process laid out in the strategy, ARS has the lead for basic research and early development of vaccines and immunomodulators (antivirals). Potential candidates are then transitioned to DHS for continued development with industry. Once appropriate products are developed, APHIS supplies them to the National Veterinary Stockpile. Interagency coordinating meetings were held as recently as May 2005 to review progress on the joint strategy.

As part of the integrated biodefense complex, the S&T Directorate operates the Plum Island Animal Disease Center (PIADC) and two Homeland Security (HS) Centers of Excellence in agricultural security described below.

Plum Island Animal Disease Center

PIADC is a critical national asset for addressing foreign animal diseases. This strategy includes programs on:

- Net assessment of the foreign animal disease threat;
- Vaccines and therapeutics:
    - Improved current vaccines (onset of immunity, adjuvants);
    - Development of next-generation vaccines and immunomodulators; and
    - Transition of promising candidates to industry partners for full product development.

- Assays and diagnostics:
    - National and international validation;
    - Enhanced diagnostics capability and surge capacity; and
    - A new bioforensics capability.

The overall goal of this strategy is to expedite the transition of new validated diagnostics to the USDA National Animal Health Laboratory Network (NAHLN) and new vaccines and immunomodulators to the USDA National Veterinary Stockpile, as well as increasing surge capacity at critical nodes of the response infrastructure.

In addition to these research and diagnostics programs, the S&T Directorate has responsibility for the maintenance and operations of the PIADC facilities, including necessary upgrades and enhancements of facilities and security.

To facilitate overall coordination of these programs at PIADC, a Board of Directors has been established which is chaired by the S&T Directorate and includes the administrators of both USDA ARS and APHIS. In addition, the Office of Science and Technology Policy's National Science and Technology Council recently established a new Subcommittee on Foreign Animal Disease Threats which is co-chaired by USDA and the S&T Directorate and provides a valuable new interagency forum for cooperation.

University Centers of Excellence

The mission of the S&T Directorate's University Programs is to stimulate, coordinate, leverage, and utilize the unique intellectual capital in the academic community to address current and future homeland security challenges and to educate and inspire the next generation of scientists and engineers dedicated to homeland security. The Homeland Security Centers of Excellence provide independent, cutting-edge research in academia for focused areas of homeland security research and development.

Established HS Centers of Excellence include those for:

- Risk and Economic Analysis of Terrorism Events;
- Foreign Animal and Zoonotic Disease Defense;
- Food Protection and Defense; and
- Behavioral and Social Aspects of Terrorism and Counter-Terrorism.

Each Center is selected on a competitive basis, and each grant is for three years. Each Center has a role in addressing bioterrorism, and two are specifically aligned with addressing agroterrorism as described below.

Texas A&M University and its partners from the University of Texas Medical Branch, University of California at Davis, and the University of Southern California will receive funds over the course of the next three years for the study of foreign animal and zoonotic diseases. The Center, known as the National Center for Foreign Animal and Zoonotic Disease Defense, is working closely with partners in academia, industry, and government

to address potential threats to animal agriculture, including FMD, Rift Valley fever, avian influenza, and brucellosis. The FMD research is being conducted in close collaboration with DHS's PIADC and includes work on new rapid diagnostics for foreign animal and zoonotic diseases.

DHS is providing the University of Minnesota and its partners, Michigan State University, University of Wisconsin at Madison, North Dakota State University, Georgia Institute of Technology, and the University of Tennessee at Knoxville with funds over the course of the next three years to establish best practices and attract new researchers to manage and respond to food contamination events, both intentional and naturally occurring. The University of Minnesota's National Center for Food Protection and Defense addresses agricultural security issues related to post-harvest food protection, including developing a prototype food event modeling system, new risk communication approaches to minimize the potential impact of food contamination events, and realistic decontamination scenarios involving surrogate agents and food matrices.

Both university centers are coordinating their efforts of those of the S&T Directorate, the IAIP Directorate and the Food and Agriculture Government Coordinating Council.

Proposals are currently under review for a fifth DHS Center of Excellence on the topic of High Consequence Event Preparedness and Response.

In addition to the University Centers of Excellence, the Department of Homeland Security's University Programs and the EPA's Science to Achieve Results (STAR) Program are reviewing proposals for a research Center of Excellence focused on an area of high priority to both agencies: microbial risk assessment for Category A bio-threat agents.

Accomplishments and Planned Activities

In FY 2004 and FY 2005, the S&T Directorate, in coordination with its USDA and HHS partners:

- Developed and submitted reports to Congress on a research strategy for foreign animal disease, as well as a comprehensive strategy for combating agroterrorism.
- Continued operation of PIADC, with essential upgrades to the facility and its security.
- Conducted end-to-end systems studies for FMD, bulk food contamination, and crop defense (soybean rust), and initiated a system study for highly pathogenic avian influenza that identify requirements, R&D gaps, potential architectures, and trade-offs for each scenario.
- Developed a national coupled epidemiological and economic model for FMD, and will conduct an internal DHS tabletop exercise for FMD during FY 2005.
- Initiated R&D programs to:
    - Characterize the current FMD vaccine bank, including the time-to-onset of the immune response;

- Evaluate preventive and therapeutic vaccine candidates for FMD;
- Establish an agricultural bioforensics capability; and
- Develop, in coordination with USDA's National Animal Health Laboratory Network, an integrated platform for high-throughput multiplexed assays for FMD that can analyze thousands of samples per day in support of response to a suspected case or an outbreak.

NATIONAL BIO AND AGRODEFENSE FACILITY

PIADC is a unique and critical facility for the nation's foreign animal disease defense and celebrated its 50th anniversary in 2004. Thus, the facility is now well beyond its originally planned life span, and is in need of recapitalization.

In FY 2005 the S&T Directorate is funding a conceptual design study for a next-generation facility, the National Bio and Agrodefense Facility (NBAF). The goal of this study is to determine the programmatic drivers for the necessary size and scope of the facility and the research and development to be conducted there. Three major programmatic themes are being considered:

- The historical PIADC mission for foreign animal disease research in livestock, with needs anticipated over the lifetime of the new facility (approximately 40 years);
- The study of zoonotic diseases, including associated requirements for specific biosafety levels of containment; and
- Testing and evaluation required for licensure of medical countermeasures in conjunction with HHS.

DHS is working closely with its interagency partners throughout this planning process, including USDA and HHS.

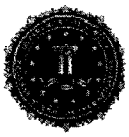
The proposed FY 2006 budget for DHS includes $23M for the architectural and engineering design and pre-construction costs of the NBAF.

CONCLUSION

The S&T Directorate's programs conducted within DHS fully support the national agrodefense program as stated in the presidential directive *Defense of United States Agriculture and Food* and other Homeland Security Presidential Directives. Moreover, they are conducted in an active collaboration with other Federal departments and agencies having a role in meeting this national priority and are focused on reducing the threat of a biological attack against this nation's agriculture and food critical infrastructures.

This concludes my prepared statement. With the Committee's permission, I request my formal statement be submitted for the record. Mr. Chairman, Senator Harkin, and

Members of the Committee, I thank you for the opportunity to appear before you today and I will be happy to answer any questions that you may have.



Remarks Prepared for Delivery by
Deputy Assistant Director
John E. Lewis
Federal Bureau of Investigation
Senate Committee on Agriculture, Nutrition, and Forestry
July 20, 2005

Good morning, Chairman Chambliss, Ranking Member Harkin, and members of the Committee. It is a pleasure to be here today.

Since September 11th, we have necessarily sharpened our focus on unconventional methods of future attacks, including the potential for agroterrorism. Most people do not equate terrorist attacks with Agroterrorism. But the threat is real, and the impact could be devastating.

Today I want to talk about what the FBI is doing to prevent, detect, and investigate threats of agroterrorism. We have been fortunate so far – we have not faced any direct large scale attacks to our food supply. We have investigated possible Agroterrorism attacks with our interagency partners, ultimately determining that these were cases of product tampering, natural disease outbreaks, or accidental events.

The absence of any direct attack on our food supply does not minimize the threat. We know that members of Al Qaeda have studied our agricultural industry along with other potential targets. In addition, some animal rights activists and environmental extremists have touted agroterrorism as a potential means to end animal testing, animal consumption, and genetic engineering.

One thing is certain: given the nature of the threat, the partnerships the FBI has developed, and that we are diligently working to expand and strengthen will go a long way toward preventing potential agroterrorism attacks.

Today, we are sharing information, technology, and resources with our federal, state, and local counterparts as well as industry.

One of the ways we are working together is through the Agricultural Intelligence Working Group. Members of this group – including the FBI, the CIA, the USDA, the FDA, the Department of Homeland Security, and the military – meet regularly to exchange information and ideas about food security, and to discuss ways in which we can best utilize our combined skills, technology, and resources to prevent an attack on our food and agriculture sector.

Another way we are working together is through various Scientific Working Groups. FBI scientists are working with their counterparts around the country. Scientists from the CDC, key laboratories around the country, the CIA, and the Department of Homeland Security, analyzes animal and plant pathogens – down to the DNA level – to distinguish between pathogens that occur in nature, and those that are intentionally spread.

This distinction is important. Recovery of the components of an improvised explosive device at the scene of an explosion can clearly indicate an intentional act has occurred. In contrast, if a cow contracts Foot and Mouth Disease or a soybean plant exhibits rust, it can be difficult, if not impossible, to determine whether the attack was intentional or occurred naturally.

We are not limiting our partnerships to the federal level. We are reaching out to the people on the front lines - farmers, cattle ranchers, food producers, and distributors.

FBI Headquarters is directing the formation of a program called Ag-Guard, as well as the formation of Agroterrorism Working Groups nationwide. The Ag-Guard program is modeled after our existing Infraguard network. Through a secure web portal, members of the agricultural community are sharing information with each other, and with scientists, state and local law enforcement, and the FBI. Members can pose questions, and alert the FBI to any suspicious or unusual activity. This program is a win-win for everyone involved. We are continuing to expand this program and expect to have a nationwide network developed in the near future.

Additionally, the FBI has formed a partnership with the DHS, USDA, FDA, and private industry to conduct site surveys of specific private industries within the agriculture industry. The intent of this Strategic Partnership Program is to determine critical points in our agricultural system that may be the target of a terrorist attack, identify early indicators and warnings that would signify planning and/or preparation for an attack, develop a focus for intelligence collection strategies around these indicators and warnings, and develop mitigation strategies for early detection, deterrence, disruption, interdiction, and prevention.

We are currently working with the Food and Agriculture Sector Coordinating Council and the Government Coordinating Council (GCC) to identify approximately 50 sites that we hope to visit over the next two years. The sites will include the entire production cycle, from farm to fork.

Now, I want to move to the FBI's detection and investigative methods. I will discuss the two together, because both rely upon the partnerships that we have established with our interagency partners.

We currently lead 105 Joint Terrorism Task Forces. These JTTFs are the focal point of our counterterrorism efforts. The JTTFs are aided in these efforts by highly trained WMD Coordinators in each field office. WMD threat related information is provided to the WMD Coordinator either via the extensive liaison network that each has established locally, or through the JTTF. The WMD Coordinator then contacts FBI Headquarters where we facilitate the interagency threat assessment process. This threat assessment process capitalizes upon the expertise of scientists and subject matter experts both within the FBI and those of our interagency partners. Our Hazardous Materials Response Unit and the 27 Hazardous Materials Response Teams they oversee in our field offices possess significant capabilities to collect and assess potential WMD materials, further enhancing our capability to provide timely input into the interagency threat assessment process. The same process is utilized in the event the threat involves a potential chemical release or agroterrorism. It is a process we utilize almost every day across the nation. We continue to expand our agroterrorism specific liaison contacts.

In order to expand this information sharing, in July of 2004, I directed field offices nationwide to identify and survey agriculture and food systems within their jurisdiction. I tasked field offices to assess the level of

interaction and coordination between the FBI and key infrastructure officials in this sector on preparedness and information sharing matters.

To further formalize the mechanism for communication of threat information and to strengthen the FBI's relationship with the food and agriculture sector, field offices were directed to establish formal Agroterrorism Working Groups within their jurisdiction. This working group will enhance the already established relationships between Federal partners by bringing together representatives from all entities involved in the areas of proactive prevention and awareness, intelligence, investigative response, and crisis management.

The Select Agent Registration Program was established to enhance the security of specific biological pathogens and toxins. Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 , the Attorney General has the responsibility to query criminal, immigration, national security, and other electronic databases to determine if an individual applying for select agent status is a restricted person.

Animal Plant Health Inspection Service (APHIS) and CDC Select Agent Program personnel have the responsibility of determining if a facility and/or an individual is properly trained and has the appropriate skills to handle the listed select agents and toxins; has proper laboratory facilities to contain and dispose of listed agents and toxins; including provisions to ensure that facilities and individuals seeking to register have a legitimate purpose to receive, possess, or transfer such agents and toxins. The FBI Criminal Justice Information Services Division (CJIS) has been designated to conduct the Security Risk Assessments (background checks) mandated under the Bioterrorism Act. CJIS processes the background checks on the facility owner/operator, the Responsible Official, and all facility employees requesting access to listed biological agents and toxins.

In the event that the background check raises additional concerns about an applicant a lead will be set to gather additional information to clarify and determine if sufficient information is available to restrict the individuals' access to listed select agents or toxins. FBIHQ will then coordinate with USDA and CDC to determine whether an applicant is restricted or not.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville, MD 20857

STATEMENT OF

ROBERT E. BRACKETT, PH.D.

DIRECTOR

CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

FOOD AND DRUG ADMINISTRATION

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY

UNITED STATES SENATE

JULY 20, 2005

FOR RELEASE ONLY UPON DELIVERY

INTRODUCTION

Good morning, Chairman Chambliss and Members of the Committee. I am Robert E. Brackett, Ph.D., Director of the Center for Food Safety and Applied Nutrition (CFSAN) in the Food and Drug Administration (FDA or the Agency), Department of Health and Human Services (HHS or the Department). I am pleased to be here today with my colleagues from the U.S. Department of Agriculture (USDA), the Department of Homeland Security (DHS), and the Federal Bureau of Investigation (FBI). FDA appreciates the opportunity to discuss our food counterterrorism activities.

A great deal has been done in the past few years to enhance the safety of the food supply. FDA has worked with food safety agencies, as well as with law enforcement and intelligence-gathering agencies, and with industry to significantly strengthen the nation's food safety 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 vulnerabilities, the creation of more effective prevention programs, new surveillance systems, and faster foodborne illness outbreak response capabilities.

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 safety and defense that we have been implementing in the last few years are the most fundamental enhancements in our food safety and defense activities in many years.

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

FDA'S ROLE IN COUNTERTERRORISM ACTIVITIES

FDA is the Federal agency that regulates everything we eat except for meat, poultry, and processed egg products, which are regulated by our partners at USDA. FDA's responsibility extends to live food animals and animal feed. 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. In addition, FDA is responsible for ensuring that the health consequences of foods and medicines are accurately and honestly represented to the public, so that they can be used as effectively as possible to protect and improve the public health.

FDA'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, including the food supply. 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 FDA's goal, working closely within HHS and with other Federal agencies, state and local governments, industry, and the public, to reduce the likelihood that an FDA-regulated product could be used to poison or otherwise terrorize 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, while FDA has the lead responsibility within HHS for ensuring the safety of food products, the Centers for Disease Control and Prevention (CDC) in HHS 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. In addition, these systems can be used to indicate new or changing patterns of foodborne illness. Because CDC also detects and investigates outbreaks of foodborne illness through its networks, CDC is able to alert FDA and USDA about implicated food products associated with foodborne illness and works closely with the agencies to take protective public health action. In keeping with its agency mission, CDC also identifies, evaluates, and provides expert scientific opinion on the effectiveness of foodborne disease prevention strategies.

COLLABORATION WITH FOOD SAFETY AND FOOD DEFENSE PARTNERS

In our food safety and defense efforts, FDA has many partners – Federal, state and local agencies, academia, and industry. We are 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 FBI to have the best information possible and to be prepared to act as needed. I also want to emphasize our close working relationships with our sister public health agency, CDC, Customs and Border Protection (CBP) in DHS, and USDA's Food Safety and Inspection Service (FSIS), our counterpart agency responsible for meat, poultry, and processed egg products. Some of our other 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 public health defense are coordinated through the HHS Secretary's Operations Center. This relationship facilitates communication between 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.

In addition, FDA's Office of Criminal Investigations (OCI) maintains professional relationships with domestic and foreign law enforcement agencies to receive and act on any information regarding the intentional contamination of FDA-regulated products. OCI has a specialized 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 serves as FDA's liaison with the intelligence community (CIA, FBI, Defense Intelligence Agency, National Counter-Terrorism Center, and others). In this liaison capacity, OCI maintains relationships and provides expert assistance on scientific, technical, or criminal issues to specialized units within those agencies. OCI field agents serve on selected Joint Terrorism Task Forces around the country and on other multi-agency counterterrorism task forces. OCI agents actively participate in daily briefings at the FBI-led National Joint Terrorism Task Force and at the Department of Homeland Security Information Analysis Infrastructure Protection. FDA also has an OCI agent assigned on a full-time basis to Interpol's office in Washington, D.C. OCI's coordination of the agency's criminal investigative matters, including those that relate to potential acts of terrorism, help to prevent, deter, detect, and interdict a terrorist attack on FDA-regulated products.

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.

The HHS and USDA Secretaries or their designees exercise key responsibilities as sector-specific agencies. DHS serves as the coordinator of the Food and Agriculture Sector within the Government Coordination Council (GCC). The GCC provides effective coordination of agriculture and food security strategies and activities, policy, and communication across government and between the government and the sector. In addition, the Council also plays a coordination role with the public health and clinical issues resulting from a terrorist act involving the food supply.

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, Department of Defense [DoD], Department of Commerce, Department of the Interior, and the Department of Justice) as well as that of state and local officials (representing agriculture, public health, and veterinary services), and the private sector (more than 100 trade associations and individual firms participate). As part of the HSPD-7 National Infrastructure Protection Plan (NIPP) development, FDA and USDA have drafted sector-specific plans, which will be finalized after obtaining additional input from states and the private sector. Using these plans as components, DHS has formulated the Interim NIPP for all sectors. The Interim NIPP is now being reviewed by sector members who are obtaining input from industry and state and local government participants. With the close working relationship of FDA and USDA and the other government

and industry collaborators, the Food and Agriculture Sector activities to protect critical infrastructure have set the organizational and operational standard for 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, during the fall of 2004, FDA issued the Food Security Surveillance Assignment to FDA field personnel and participating state authorities to conduct food defense-related inspections, reconciliation examinations, and collections and analyses of samples of food products that have an elevated risk for intentional contamination. The purpose of this assignment was to deter intentional contamination of food through heightened and targeted preventive activities and to identify and address any gaps in the system for responding to a period of increased food security risk. This assignment enhanced both FDA's and our state counterparts' preparedness for a future threat involving an FDA-regulated product.

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

IMPORTS

In Fiscal Year (FY) 2005, FDA has the challenge of reviewing and/or inspecting more than 9 million imported food entries. In recent years, we have expanded FDA's presence at ports of entry, increased surveillance of imported foods, increased domestic inspections, and enhanced our laboratory analysis capacity. To manage the ever-increasing volume of imported food shipments, we are working to utilize more 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 primarily to CBP, FDA screens shipments electronically to determine if the shipment meets identified criteria for physical examination or sampling and analysis or warrants other review by FDA personnel. This electronic screening allows FDA to concentrate its limited physical inspection resources on what appear to be higher-risk shipments while allowing lower-risk shipments to proceed into commerce after the electronic screening.

IMPLEMENTATION OF THE PUBLIC HEALTH SECURITY AND BIOTERRORISM PREPAREDNESS AND RESPONSE ACT OF 2002 (BIOTERRORISM ACT)

Subtitle A of Title III of the Bioterrorism Act provided the Secretary of Health and Human Services with new authorities to protect the nation's food supply against the threat of intentional contamination and other food-related emergencies. This legislation represents the most fundamental enhancement to our food safety authorities in many years. These additional authorities improve our ability to act quickly in responding to a threatened or actual terrorist attack, as well as other food-related emergencies. Since this legislation was signed into law three years ago, FDA has been working hard to implement this law effectively and efficiently. Throughout this process, FDA has enjoyed close cooperation from our colleagues at CBP. I would now like to describe FDA's actions to implement several of the provisions in the Bioterrorism Act.

Registration of Food Facilities

Section 305 of the Bioterrorism Act requires registration of foreign and domestic food facilities that manufacture, process, pack, or hold food for consumption by humans or animals in the U.S. Thanks to this provision, FDA has, for the first time, a roster of foreign and domestic food facilities that provide food for American consumers. In the event of a potential or actual terrorist incident or an outbreak of foodborne illness, the registration information will help FDA to quickly identify, locate, and notify the facilities that may be affected.

On October 10, 2003, FDA and CBP jointly published an interim final regulation to implement the registration requirement, which became effective on December 12, 2003. We currently are working to finalize the rule and hope to publish it soon. To date, 261,391 facilities have registered. This includes 114,462 domestic and 146,929 foreign facilities.

Prior Notice of Imported Food Shipments

Section 307 of the Bioterrorism Act requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the U.S. This advance information enables FDA, working closely with CBP, to more effectively target inspections at the border to ensure the safety of imported foods before they move into the U.S. On October 10, 2003, FDA and CBP jointly published an interim final rule to implement this provision. The interim final rule provided stakeholders an additional opportunity to comment on all provisions of the interim final rule while the rule took effect on December 12, 2003, as required by the Bioterrorism Act. We currently are drafting the final rule that responds to the timely comments we received and intend to publish the final rule as expeditiously as possible. Since December

2003, we have been receiving approximately 180,000 notifications each week about articles of food being imported or offered for import into the U.S.

With the prior notice requirement, specific information mandated by the Bioterrorism Act must be submitted to FDA before the imported food arrives in the U.S. This not only allows FDA's and CBP's electronic screening systems to review and screen the shipments for potential serious threats to health (intentional or otherwise) before food arrives in the U.S., but it also allows FDA staff to review prior notice submissions for those products flagged by the systems as presenting the most significant risk and determine whether the shipment should be held for further investigation. FDA worked very closely with CBP in developing this screening system.

In addition, FDA has been actively working with the analysts at CBP's National Targeting Center to utilize their Automated Targeting System as a supplementary tool to enhance the Agency's ability to focus attention on those imported foods that may pose a serious threat to public health. Products identified as "high risk" through FDA's screening criteria are targeted and undergo a manual, comprehensive "import security review" that includes a review of CBP databases that flag sensitive criminal and terrorist-related information. FDA uses defined risk factors to select candidates for import security reviews, based on intelligence reports and information about the shipper and/or consignee that indicate a potential risk to the U.S. consumer and the domestic market. Prior Notice import security reviews complement the traditional import field examinations. In FY 2004, FDA conducted intensive prior notice import security reviews on 33,111 imported food shipments.

Administrative Detention

Section 303 of the Bioterrorism Act gives FDA authority to administratively detain any article of food for which the Agency has credible evidence or information that the food presents a threat of serious adverse health consequences or death to humans or animals. This authority was self-executing and provides an added measure to ensure the safety of the nation's food supply. Section 303 also requires FDA to provide by regulation procedures for instituting on an expedited basis certain enforcement actions against perishable foods subject to a detention order. On June 4, 2004, FDA published a final rule to implement this section. The rule also includes procedures for detaining an article of food, expedited procedures for detaining perishable foods, and the process for appealing a detention order.

Maintenance and Inspection of Records for Foods

Section 306 of the Bioterrorism Act authorizes FDA to have access to certain records when the Agency has a reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals. It authorizes the Secretary to publish regulations to establish requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. On December 9, 2004, FDA published a final rule to implement this section. The recordkeeping regulation enhances FDA's ability to track and contain foods that pose a threat of serious adverse health consequences or death to American consumers from accidental or deliberate contamination of food. Affected persons must be in compliance with the regulation between December 2005 and

December 2006, based on the size of the business, with small businesses having more time to comply to enable them to learn from the experiences of their larger counterparts.

Authority to Commission Other Federal Officials to Conduct Inspections

Section 314 of the Bioterrorism Act authorizes the Secretary to commission other Federal officers and employees to conduct examinations and investigations. Pursuant to this new authority, FDA and CBP have signed a Memorandum of Understanding to commission CBP officers to conduct examinations and investigations pursuant to information obtained through the prior notice requirements. These examinations and investigations may be carried out on FDA's behalf at ports where FDA may not currently have staff or to augment FDA staff at ports that do have an FDA presence. This unprecedented FDA-CBP collaboration significantly strengthens our ability to secure the border while ensuring the movement of legitimate trade. In accordance with this authority, FDA has already commissioned over 8,150 CBP officers. The Agency will continue to explore use of this authority with other agencies with whom we share jurisdiction over a facility as a tool to further improve efficiencies.

INDUSTRY GUIDANCE AND PREVENTIVE MEASURES

FDA has issued guidance on the security measures the food industry may take to minimize the risk that food will be subject to tampering or other malicious, criminal, or terrorist actions. We have issued such guidance, "Security Preventive Measures Guidance Documents," for food producers, processors, and transporters, for importers and filers, for retail food stores and food service establishments, and for cosmetic processors and transporters. In addition, we have

issued specific security guidance for the milk industry. During domestic inspections and import examinations, FDA's field personnel, as well as our state counterparts, continue to hand out and discuss these guidance documents to firms that have not previously received it.

To help reduce the risk of an attack on the food supply, FDA and our partners at USDA have joined forces to provide a 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

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

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

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

FDA is continuing to update and refine these assessments regarding the vulnerability of FDA-regulated foods to intentional contamination from biological and chemical agents. These refinements, using a method called CARVER+Shock, use processes adapted from techniques developed by DoD for use in assessing the vulnerabilities of military targets to asymmetric threats. Results of these updated assessments will be used to develop technology interventions and countermeasures, identify research needs, and provide guidance to the private sector.

For example, 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 their 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 four segments of the regulated industry that involve bottled water, fluid dairy products, juice products, and infant formula. FDA is in the process of collaborating and providing technical assistance in assessments to a number of other food product industries using this tool. FDA also has collaborated with USDA to provide assistance to the USDA Food and Nutrition Service on the use of this analytical tool on specific commodities in the school lunch program.

EMERGENCY PREPAREDNESS AND RESPONSE

FDA has established an Office of Crisis Management to coordinate the preparedness and emergency response activities within FDA and with our Federal, state, and local counterparts. Over the past few years, FDA has participated in and conducted multiple emergency response activities including exercises coordinated with other Federal and state agencies. For example, FDA and USDA's FSIS have focused on strengthening our working relationships through joint testing of several response plans in an exercise environment. FDA has participated in numerous exercises, including those sponsored by USDA/APHIS, that focus on the occurrence

of natural or intentional outbreaks in animals. We have conducted exercises to test our emergency response with respect to contamination of the food supply and animal feed. FDA also has reviewed food defense and rapid response and recovery procedures with industry groups and trade associations.

To enhance FDA's ability to manage, plan for, and respond to food emergencies, FDA has implemented the Emergency Operations Network Incident Management System (EON IMS), an electronic system for managing emergencies. It has three components: incident tracking and contact management, a collaboration and knowledge management tool for meetings and document management, and a Geographic Information System for mapping and impact assessment. The EON IMS is important in all emergencies and exercises requiring efficient receipt and dissemination of large volumes of information to our stakeholders, including the public and other Federal and state agencies. Once completed, this system will provide a web-based connection for all FDA offices and our partners, through which accurate real-time information about various incidents can be shared and discussed. It will be a component of a safety net that enhances our ability to prepare for a terrorist attack and respond should an attack occur. The development of this system conforms to HSPD-5, "Management of Domestic Incidents." The President's FY 2006 budget requests an additional $1.5 million to support this system.

LABORATORY ENHANCEMENTS

An additional step in enhancing our response capability is to improve our laboratory capacity. A critical component of controlling threats from deliberate food-borne contamination is the ability to rapidly test large numbers of samples of potentially contaminated foods for a broad array of biological, chemical, and radiological agents. To increase surge capacity, FDA has worked in close collaboration with 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. The President's FY 2006 budget requests an increase of $20 million to support this network. As of June 2005, there are 114 laboratories representing 48 states and Puerto Rico which have expressed interest in participating in FERN, including eight Federal agencies, thus providing a framework to build upon. Participation continues to grow. Once completed, FERN will encompass a nationwide network of Federal, state, and local laboratories capable of testing the safety of thousands of food samples, thereby enhancing the nation's ability to swiftly respond to a terrorist attack.

We also are expanding Federal, state, and local involvement in our eLEXNET system by increasing the number of laboratories around the country that participate in this electronic data system. eLEXNET is a seamless, integrated, web-based data exchange system for food testing information that allows multiple agencies engaged in food safety activities to compare, communicate, and coordinate findings of laboratory analyses. It enables health officials to assess risks and analyze trends, and it provides the necessary infrastructure for an early-warning system that identifies potentially hazardous foods. At present, there are 113 laboratories

representing 50 states and the District of Columbia that are part of the eLEXNET system. We are continuing to increase the number of participating laboratories. Moreover, the governments of Canada, Mexico, and the United States agreed to establish a pilot to use eLEXNET to share food sample data among the three countries' laboratories. FDA has been working with Mexico and Canada to establish a secure network to facilitate the sharing of food-testing data between U.S., Mexican, and Canadian laboratories.

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

In addition, FDA collaborated with the U.S. Department of the Army to design and develop two mobile laboratories to be deployed at borders, ports, or other locations, to enhance our ability to provide timely and efficient analyses of imported food. The construction of these mobile laboratories has been completed, and they are capable of being deployed.

RESEARCH

To prioritize research needs and avoid duplication, FDA coordinates with its sister agencies within HHS, such as CDC, and with other Federal partners such as USDA, DHS, DoD, and the Department of Energy. Within FDA, we have embarked on an ambitious research agenda

throughout the Agency to address potential terrorist threats. To enhance food defense, FDA has significantly redirected existing research staff to ensure that appropriate resources are focused on priority food safety and defense issues. For example, research sponsored by FDA's CFSAN is aimed at developing the tools essential for testing a broad array of food products for a multiple number of biological and chemical agents. We are actively working with our partners in government, industry, and academia to develop such methods. FDA's work with AOAC International, an association of analytical chemists, on validating analytical methods for the detection of biological, chemical, and radiological agents in foods is considered the "gold standard" against which other validations programs are judged. Likewise, FDA's research on microbial genomics and analytical chemistry is widely recognized for its importance to other Federal agencies charged with forensic investigations of terrorism events.

Section 302(d) of the Bioterrorism Act directs FDA to provide for research on tests and sampling methodologies designed to test food to detect adulteration rapidly, particularly methodologies that detect intentional adulteration and tests that are suitable for inspections of food at ports of entry to the United States. This section also requires the Agency to report annually to Congress on its progress. FDA has submitted its second annual report to Congress. It can be found on FDA's Bioterrorism Act webpage.

FDA began redirecting its research program to address food defense concerns soon after the events of September 11, 2001. The report mentioned above describes more than 100 intramural and extramural research projects to develop tests and sampling methodologies for the detection of adulterated food. The Agency's research agenda is particularly focused on methods to detect

high-priority biological agents (e.g., *Clostridium botulinum* neurotoxins) as well as chemical (e.g., ricin), and radiological threat agents that pose the greatest threats to the public and is focused on foods believed to be the most vulnerable or attractive to terrorists. Our researchers also are exploring food-testing protocols using the latest technologies, such as the optical affinity biosensor technology and the quadruple time of flight mass spectrometer, to improve timeliness and accuracy over existing techniques. Researchers are also gleaning information on test methods by using them in studies focused on interventions or shields for the food supply, studies focused on characterizing the behavior (growth, survival, stability) of agents in various food categories, and studies focused on decontaminating food processing facilities.

Among the Agency's research accomplishments are the development, adaptation, or validation of rapid and field-deployable methods to detect various agents in food and the establishment of testing protocols. FDA has shared these new data and technologies with Federal, state, and local entities to equip them to perform food safety testing.

CONCLUSION

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

Thank you for this opportunity to discuss FDA's counterterrorism activities to protect the food supply. I would be pleased to respond to any questions.

Senator Ken Salazar
Regarding Biosecurity Preparedness and Efforts to Address Agroterrorism Threats
July 19, 2005
Statement

Chairman Chambliss and Ranking Member Harkin, thank you for holding this hearing on the issue of agroterrorism, which is of such great importance to our agricultural producers and industries, our food industries and our consumers across America and around the world. I also want to thank this panel of distinguished witnesses for their testimony today and I look forward to working with all of you on this important issue.

The security of our food and agricultural sectors is essential. The food industry contributes more than $1 trillion to our Gross Domestic Product. The agricultural industry contributes more than $5 billion a year to Colorado's economy and is the backbone of our rural communities.

September 11th brought with it the harsh realities of the potential for terrorist attacks in our own country, and it is extremely important that we are here today to talk about another potential reality which is the threat of agroterrorism.

Late last year, outgoing HHS secretary Tommy Thompson warned that we were extremely vulnerable to an agroterrorism attack, saying the threat, worried him "every single night." He was right to worry.

An attack on our livestock, crops or food supply could endanger many lives and devastate our economy. An outbreak of avian flu in Asia killed 42 people, and the United Kingdom is still trying to recover from an outbreak of Foot and Mouth Disease that cost its economy more than $5 billion. American agriculture, with its massive concentrations of livestock breeding and feeding is particularly vulnerable to an attack.

Congress and the executive branch have taken a number of important steps to consolidate and strengthen our defenses against agroterrorism. I commend USDA, FDA and the Department of Homeland Security for taking aggressive steps to improve incident management, expand our laboratory capacity, examine our vulnerability and increase investment in agroterrorism research.

The people who are testifying today have struggled with these issues for years, and have brought us light years forward in our efforts to prevent, detect and respond to agroterrorism.

However, it is clear that our agroterrorism defense is very much in its infancy. We are not inspecting enough of the agricultural products that are entering this country. A recent GAO report found that agricultural inspections decreased 3.4 million per year between fiscal years 2002 and 2004. DHS inspectors are undertrained to identify threats to our agriculture. We do not have enough capacity to identify sick animals in the field. And, our vaccine stockpile is woefully inadequate as is our system for deploying vaccines.

Clearly, there is much to be done. I am very pleased that we are having this hearing today. I look forward to the testimony and to listening to the advice of these witnesses about what we are doing and need to do to ensure that our agricultural industry and food supply remains the safest and best in the world.

Testimony for the United States Senate Committee
on Agriculture, Nutrition, and Forestry

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July 20, 2005

Thank you for inviting me here today to comment on biosecurity preparedness and efforts to address agroterrorism threats posed by plant diseases that impact the food, feed and fiber of our nation. My name is John L. Sherwood and I am a Professor and Head of the Department of Plant Pathology at the University of Georgia. I am also representing the American Phytopathological Society (www.apsnet.org), a scientific organization of 5000 members that includes national and international scientific leaders and houses the collective expertise to mitigate the impact of introduced plant disease agents. Our member scientists are employed by universities, private industry, and agencies within the State and Federal governments.

The U.S. has been blessed with vast tracks of land that have provided an abundance of food, feed and fiber. At times plant diseases have had significant economic and social impact on our society: these have included wheat rust early in the last century, the chestnut blight of the 1930s, corn leaf blight in the 1970s, and Fusarium head blight of small grains in the 1990s. Today, the community of scientists in research, education, extension and regulatory policy are facing soybean rust and sudden oak death, among other diseases that affect the vitality of our fields and forests. As with diseases affecting animals and humans, new diseases of plants are encountered regularly here and abroad and require detection, diagnosis, investigation and control. Positive steps to protect U.S. crops have been taken. Examples are the nascent National Plant Diagnostic Network, the regulatory activities toward mitigating exotic pathogens by APHIS and State Departments of Agriculture, the EPA approval of Section 18 requests to provide expanded management tools to minimize the potential economic damage caused by soybean rust, and the establishment or revitalization of crop biosecurity panels or centers within various governmental agencies.

Securing our nation's crop production systems requires a multi-faceted, multi-agency, and highly-coordinated effort. The four key components of an effective approach to mitigate acts of crop terrorism and maintain safe and productive crop systems are **strategic anticipation** of potential threats, **prevention** of a bioterrorist attack, **preparedness** to respond to an attack, and **coordination** of these strategies.

Strategic Anticipation

The foundation of security is identifying potential threats. Because our cropping system is so diverse and complex, predicting which exotic pathogens pose the greatest risk and preparing for their arrival are not trivial tasks, especially as new pathogens are encountered frequently. However, these activities are the role of the science of plant pathology. Each year scientists in the public and private sector prepare to thwart diseases that may affect our nation's plant production systems. Fundamental to any aspect of plant biosecurity is understanding the biology of how plants get sick. This is why support of basic and applied research through the

competitive grants process is essential for the security of our nation's feed, food and fiber production systems.

Sustained funding in support of strategic anticipation will result in:

- Greater awareness of the existence, location, spread, biology and management of exotic, offshore pathogens that pose significant threats to U.S. crops, thus providing opportunities to preemptively prepare for their arrival.
- Understanding and incorporation of broad-spectrum disease resistance in crop species to protect against exotic pathogen introduction.
- A comprehensive view of how microorganisms interact in natural habitats to determine the natural processes of plant disease suppression through a combination of genomic, molecular, and ecological approaches.
- New chemicals to combat disease that will be used at low application rates, pose minimal environmental risk, and have a low potential for the development of pathogen resistance.
- Preservation of talented and trained human resources to effectively respond to pathogen outbreaks whether of natural or deliberate origin.

Prevention

Prevention efforts must be directed towards securing the nation's 127 designated points of entry, as well as the length of our country's natural borders, against the passage of pathogens not yet in the U.S., whether such passage is natural or intentional. Currently, much effort is spent regulating pathogens that are widespread and endemic in the U.S. These pathogens pose no more threat in regard to biosecurity than they annually cause in naturally occurring epidemics. Such natural epidemics may be devastating in a given locale during any growing season, but extensive regulation of such endemic pathogens limits the ability of the scientific community to investigate and develop appropriate management strategies, and results in squandered resources.

Prevention can become a meaningful strategy with resources and support to:

- Fully consider the implications of placing a pathogen on a priority list, since such a listing introduces significant constraints on handling, research, and scientific communications, all of which are activities needed for optimizing prevention and preparedness. Determining the risk/benefit of listing pathogens is now under consideration by the recently established National Scientific Advisory Board for Biosecurity, and should be determined after consideration of input from both Federal agencies and the larger scientific community.
- Develop a process for regular and timely review of pathogen priority lists based on scientific knowledge of pathogen virulence and fitness, disease epidemiology and impact, and plant host value and susceptibility. Such review is necessary to determine the feasibility of initiating research programs and conducting management trials to mitigate ingress of an exotic pathogen into the U.S.
- Prevent either an unintentional escape or unauthorized access to those select agents that pose significant risk to U.S. agriculture and that are stored or handled in U.S. research laboratories. However, research must be continued on such pathogens to assure

preparedness. Thus, current and planned expensive BSL-3 facilities should be reserved for pathogens of highest risk. Other workplaces, where an inadvertent release of a lesser-risk pathogen would not affect any cropping system due to spatial and temporal parameters should be established. Such places would include climates in which the pathogen cannot survive outside the research facility or in which no plant host is grown.

It is critical to focus limited financial and research resources on the plant pathogens of greatest concern, and to determine the most effective detection and identification tools for these pathogens. Effective communication between Federal agencies and scientific societies, such as the APS, will provide a solid foundation to prioritize these needs.

Preparedness

Although a strong program to prevent introductions of exotic or modified pathogens is fundamental to the security of our crop production systems and will reduce the likelihood of such an event, the sheer numbers of crops and their associated or potential pathogens make 100% prevention impossible. Thus, we must be prepared for the introduction of pathogens that elude such efforts. An effective preparedness program is dependent upon: 1) scientific openness, 2) teamwork and networking, 3) communication at all levels (first line responders, scientists, law enforcement, and the public), (4) anticipatory research programs, and (5) investments in infrastructure.

The recent establishment by USDA-CSREES of the National Plant Diagnostic Network (NPDN), a network of five regional plant diagnostic laboratories, dispersed among the land grant universities, that is working to establish coordinated efforts with APHIS, State Departments of Agriculture, and private seed companies, is an important step in building a preparedness infrastructure.

For the NPDN to be optimally effective many critical issues must be addressed:

- Research support for detection techniques with greater speed, sensitivity and discriminatory capacity to facilitate determining whether an event is accidental or deliberate, and whether the causal agent is a high-risk, non-indigenous pathogen, a more virulent strain of an extant pathogen or an unknown pathogen. The lag time from the introduction to the discovery of a bioterrorist introduction must be minimized, and we must be able to monitor pest occurrence and spread in real-time.
- Enhanced attention to, and investment in, strategies for effective forensic analysis and criminal attribution to bring perpetrators to justice and to serve as a deterrent.
- Continued implementation of training programs and reporting incentives for first responders.
- Enhanced research capacity and support to develop a greater understanding of disease epidemiology and the genetic structure and phylogeny of pathogens around the world.
- Communication and response plans for handling intense interest from the public and the media if an outbreak should occur.

Coordination

Many elements necessary for an effective national readiness and response plan in crop biosecurity are coming into place. The National Biodefense Analysis and Countermeasures Center (NBACC), recently established by the Department of Homeland Security and housed at Fort Detrick, MD, is charged to integrate national resources for homeland biosecurity, drawing on resources from public health, law enforcement, and national security. It will provide an interdisciplinary capability to better defend against the full range of human, animal, and plant BSL-3 and BSL-4 biothreat agents. While the greatest consideration must be given to threats that directly impact human and animal health, we emphasize that long-term human and animal health is dependent on a sustainable agriculture production system in the U.S. In addition to endangering the production of food and fiber, the arrival of exotic plant pathogens could negatively impact world trade, and cause financial losses to our fragile rural economies. To ensure sustainable production systems into the future, long term investments by agencies in support of research on plant pathogens are critical and should not be limited to those being on a particular "list." While those may be of most concern, an understanding of similar diseases can give insight on how to manage those of greatest concern.

However, still lacking today are effective communication, coordination and strategic planning among the many entities that are charged with protecting plant health. In the fall of 2004, following two years of planning and solicitation of stakeholder input, the APS released its proposal for the establishment of a national center to coordinate efforts in crop biosecurity. APS has proposed that this **National Center for Plant Biosecurity** (NCPB) be established within the USDA as a Federal coordinating office staffed by Federal employees and administered at the level of the Office of the Secretary of Agriculture. This proposal has received wide support and endorsed by the Entomological Society of America, the American Society of Agronomy, the Crop Science Society of America, the Soil Science Society of America, the Society of Nematologists, and the Council for Agricultural Science and Technology. The NCPB will provide a single point of contact for the enhancement, and coordination of current and future efforts relating to defense against bioterrorist attacks, major disasters, and other emergencies, such as the recent introduction of soybean rust into the U.S. The NCPB also will provide a strong framework and leadership for anticipating, detecting, responding to, managing, and recovering from such events, as mandated in presidential directive HSPD-9, which calls for a **National Plant Disease Recovery System**.

Many of the critical functions of a plant biodefense system are currently the responsibility of various Federal, State and non-governmental agencies, centers, and programs. The Federal NCPB will not duplicate those efforts, but rather it will build on and coordinate these existing resources and capabilities to provide a state-of-the-art national infrastructure for documenting, monitoring, and protecting U.S. agriculture against the threat of new or emerging plant diseases and pests. This is why the APS has recommended that the NCPB report directly to the Office of the Secretary of Agriculture rather than be embedded within an existing agency. The NCPB will function as a visionary, strategic planning and coordinating entity and will be linked directly to USDA agencies and staff responsible for plant biosecurity, and closely to DHS offices responsible for biosecurity. The roles of the NCPB will be equally applicable to naturally-occurring plant-related events, such as the recent introduction into the southern United States of soybean rust, an agent then listed on the USDA-APHIS threat list.

The establishment of the NCPB will:

- Provide overarching coordination of all plant biosecurity activities by all Federal agencies.
- Provide a single point of contact with the Federal government on matters affecting plant biosecurity.
- Provide leadership during specific breaches of biosecurity or major disasters related to plants and help clarify which Federal agency has jurisdiction over different aspects of such events.
- Foster communication and synergies among government, private, and professional entities.
- Identify resource needs for surge capacity in reacting to suspected or actual events.
- Ensure that the goals and objectives of the various plant biosecurity programs are implemented by the agency charged with programmatic responsibility.
- Build on, support, and enhance existing and newly developed facilities and capabilities for detection, diagnosis, and communication with respect to incidents or threats to plant security.
- Collaborate with other agencies and organizations to conduct frequent vulnerability assessments.
- Develop strategic plans for addressing vulnerabilities identified in such assessments and long-term strategic plans for enhancing and expanding activities for effective mitigation of threats from biological agents.
- Act in concert with existing agencies charged with the protection of critical nodes of agricultural commodity production and processing and other entities to develop and regularly review response and recovery plans.
- Ensure the development of educational and training programs and materials for potential "first detectors" and "first responders."
- Identify and support targeted research initiatives that enhance the country's ability to prevent, detect, respond to, and recover from the introduction of a threat agent, including the identification and prioritization of needed research on threatening plant diseases and pests.

Conclusion:
The geographical expanse and economic importance of the U.S. agriculture enterprise creates a vulnerability to the intentional or unintentional introduction of plant pathogens that could directly affect crop yields and the viability of our crop production systems. While the nation will respond to and recover from such an event, there is likely to be an erosion of citizen confidence in a safe and secure supply of food, feed and fiber. New investments in the infrastructure and resources necessary to protect and maintain plant health will have significant social and economic benefit, both in the immediate future and for the generations to come.

TESTIMONY BEFORE THE UNITED STATES SENATE COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY
Wednesday, July 20, 2005

Presented by James A. Roth, DVM, PhD, Director, Center for Food Security and Public Health, Iowa State University, College of Veterinary Medicine, Ames, Iowa

Chairman Chambliss, Senator Harkin and members of the Senate Committee on Agriculture Nutrition, and Forestry, thank you for holding this important hearing today and for the opportunity to testify before you. I am the director of the Center for Food Security and Public Health. Our mission is to increase national preparedness for accidental or intentional introduction of disease agents which threaten food security or public health.

U.S. agriculture is highly vulnerable to the accidental or intentional introduction of foreign and emerging animal diseases. Many of these diseases are zoonotic (they also infect people) and can cause serious public health problems, including loss of life. Diseases that affect both animals and people are more difficult to control. In recent years, there have been numerous examples of accidental introductions of foreign animal and zoonotic diseases worldwide. Because agriculture accounts for 13% of the U.S. gross domestic product and 18% of domestic employment, an outbreak of a foreign animal or zoonotic disease could be devastating to the US economy. This makes agriculture an attractive target for terrorists.

Animal agriculture is also threatened by the potential bioterrorism agents, since nearly all of them are zoonotic. Agents against animals have been considered as a component of nearly every nation-sponsored offensive biowarfare program. The U.S. is not adequately prepared to respond to animal agricultural issues, companion animal issues, or wildlife issues in bioterrorism events. Concerns about the level of preparedness for accidental or intentional introduction of diseases have been identified by individuals at all levels of federal and state governments and by animal industry and public health officials.

Since the outbreak of foot and mouth disease in the U.K in 2000, the events of September 11, 2001, and the anthrax bioterrorism event, the U.S. Department of Agriculture (USDA), the Department of Health and Human Services (HHS), and the Department of Homeland Security (DHS) have worked to increase preparedness for disease outbreaks. Significant progress is being made. The national animal ID system is being developed, expert working groups have been convened to establish research and vaccine development priorities, a number of states have organized or are working to organize animal emergency response teams, veterinary diagnostic laboratories are networking to enhance the national capacity and to better share information, and Congress has nearly completed funding for the modernization of the National Centers for Animal Health in Ames, Iowa.

Despite the progress, the U.S. continues to have inadequate infrastructure for prevention, detection, response and recovery for foreign animal and zoonotic diseases. Homeland

Security Presidential Directive 9 (HSPD 9), Defense of U.S. Agriculture and Food, issued on January 30, 2004 addressed some of the challenges and needs. However, funding to implement a number of critically important items in the Directive has not been made available.

The significant challenges that I will focus the rest of my testimony on are the vulnerabilities and needs I consider the most important for protecting public health, animal health, and U.S. agriculture from disease threats. These priorities include the rapid development of vaccines and anti-virals for high priority foreign and zoonotic diseases; correcting major deficiencies in the physical capacity for animal health research and disease diagnosis in the U.S.; and strengthening the human resources needed to prevent, prepare for, respond to, and recover from a devastating foreign animal or zoonotic disease event.

Vaccines and Anti-Virals for Foreign Animal and Zoonotic Disease Defense

In 2003, two expert panels were convened by the Federal government to assess the threat from animal pathogens that could be used by bioterrorists or agroterrorists, and to establish research and development needs to reduce the threat from these agents. The *Interagency Weapons of Mass Destruction (WMD) Counter Measures Working Group – Animal Pathogens Research and Development Subgroup (2003)* and a *White House Office of Science and Technology Policy (OSTP) Agroterrorism Countermeasures Blue Ribbon Panel (Dec 2003)*, identified 10 animal diseases to be of highest priority for vaccine and anti-viral research and development: foot and mouth disease, Rift Valley fever, highly pathogenic avian influenza, Nipah/Hendra, exotic Newcastle disease, classical swine fever, African swine fever, Venezuelan and eastern equine encephalitis, and rinderpest. The expert groups recommended significant investments in vaccine and anti-viral research and development to mitigate the threat from these agents.

HSPD 9 calls for the creation of a National Veterinary Stockpile (NVS) containing significant amounts of animal vaccine, antiviral or therapeutic products to appropriately respond to the most damaging animal diseases affecting human health and the economy. The NVS should be capable of deploying vaccines within 24 hours of an outbreak. Rift Valley fever (RVF), Nipah virus, and avian influenza are especially significant threats because of their contagious nature and the fact that they can cause serious illness and death in humans. Sufficient data exists to demonstrate that safe and effective vaccines for these three diseases can be developed in a short time frame. A relatively modest investment could result in the development and production of vaccines for these three diseases for the NVS. This preventive measure would effectively reduce the serious threat these diseases pose to both public health and animal agriculture.

Animal vaccines can be developed for a small fraction of the cost of developing human vaccines, and can be approved for use much quicker and with less risk than human vaccines. Vaccinating animals for zoonotic diseases effectively protects the human population from infection, and reduces the need to vaccinate people. This results in huge cost savings and avoids the safety concerns associated with vaccinating people.

Project Bioshield calls for $5.6 billion over a 10 year period for the development of vaccines and therapeutics for use in humans. A portion of that funding should be designated to develop vaccines and other preventatives for animal diseases with zoonotic importance. This will effectively reduce exposure of humans to these diseases, provide protection much sooner than is possible through the development of human vaccines, and reduce the need to vaccinate humans.

Physical Infrastructure for Foreign Animal and Zoonotic Disease Defense

The core of the federal government's scientists, support staff and laboratories dedicated to research and diagnosis of foreign animal diseases that threaten U.S. livestock are currently located at the Plum Island Animal Disease Center on Plum Island, NY. These facilities are operated by the Department of Homeland Security and staffed by USDA scientists responsible for research and diagnostic activities. The Plum Island Animal Disease Center does not have adequate capacity for the foreign animal disease research and diagnostic needs of the nation. This lack of capacity is recognized by the USDA, the Department of Homeland Security, the American Veterinary Medical Association (AVMA), the Association of American Veterinary Medical Colleges (AAVMC), the U.S. Animal Health Association and other groups. **Planning should begin immediately for replacement of the Plum Island Animal Disease Center facilities and funding for new facilities should be appropriated as soon as possible.**

Additional biosafety level 3 agriculture (BL3 Ag) and biosafety level 4 (BL4) facilities for animal health research are urgently needed. There are no BL4 facilities for livestock disease research in the U.S. I am currently coordinating a project to develop a vaccine for the Nipah virus, a BL4 pathogen which causes serious illness and death in pigs and in people. Our collaborators in Canada are using their BL4 facility to test the vaccine in pigs because the U.S. does not have facilities for this research in food animal species.

Human Resources for Foreign Animal and Zoonotic Disease Defense

Veterinarians are an integral part of the nation's public health system. Nearly all of the biological agents that pose the highest risk to national security cause diseases that are transmitted from animals to man; veterinarians have expertise in diagnosing, preventing and controlling these types of diseases. There is a serious and acute shortage of veterinarians in rural agricultural areas, federal government agencies, and in disciplines such as public health and food safety. There is also a critical shortage of DVM, PhD research scientists and teachers to train future scientists, especially in high priority areas of veterinary infectious diseases.

The **National Veterinary Medical Service Act** was signed by President Bush in December 2003 in recognition of the severe shortage of food animal veterinarians in rural areas. The Act authorizes the Secretary of Agriculture to "conduct a loan repayment program regarding the provision of veterinary services in shortage situations, and for other purposes." However, there is no funding to support this Act. Approximately $20 million per year is needed for this program.

In May 2005, U.S. Senator Wayne Allard of Colorado introduced S. 914, the **Veterinary Workforce Expansion Act of 2005** (VWEA). The proposed legislation would establish a grant program to expand capacity in veterinary medical schools, and increase the number of veterinarians working in public health practice and biomedical research. The VWEA would amend the Public Health Service Act to create a competitive grant program for schools and institutions to increase both their training capacity and their ability to research high-priority diseases. Veterinary colleges are a critical national resource but are only supported by 27 states. The nation's professional veterinary education capacity has not changed appreciably in 20 years and it has been nearly 30 years since the federal government has provided general funding for veterinary medical colleges. Studies by the AAVMC have shown that approximately 350 additional students are needed each year in order to maintain the current ratio of nine incoming veterinary students per million people. The AAVMC and the AVMA are supporting this pending legislation.

Funding of the National Veterinary Medical Services Act and the Veterinary Workforce Expansion Act of 2005 is critical to developing the human resources needed for foreign animal and zoonotic disease defense.

Additional funds should be made available for advanced training of veterinarians in infectious disease related disciplines. A 2003 (AAVMC) survey found 149 vacant positions in veterinary pathology, with a projected shortage of 60 veterinary pathologists per year, and 200 vacancies for DVMs in the USDA-Food Safety Inspection Service.

In summary, progress has been made in increasing our preparedness for agroterrorism events and incursions of foreign animal and zoonotic diseases, but much remains to be done. Vaccines and anti-virals for high priority foreign animal and zoonotic diseases should be developed as quickly as possible and placed in the National Veterinary Stockpile. Planning should begin immediately for replacement of the Plum Island Animal Disease Center facilities with the addition of BL4 facilities for domestic animal research, and funding for these facilities should be appropriated as soon as possible. In order to develop the human resources needed for foreign animal and zoonotic disease defense; funds should be appropriated for the National Veterinary Medical Services Act and the Veterinary Workforce Expansion Act of 2005.

Testimony

James Lane, Ford County Undersheriff, Dodge City, Kansas

concerning

Bioterrorism Preparedness and Efforts to Address Agroterrorism

before

Agriculture, Nutrition and Forestry Committee
United States Senate
Washington, D.C.

July 20, 2005

Oral Testimony

Mr. Chairman and members of the committee; I am honored to provide testimony concerning the threats of agroterrorism and ongoing efforts to protect American agriculture. Thank you for this opportunity.

My remarks today will be from the *local* law enforcement perspective. I will offer the committee an overview of the agroterrorism preparedness activities that are occurring at the local level in the state of Kansas. Further, I will speak briefly about our experiences, interaction, and initiatives with state and federal officials. I want to emphasize that we are never satisfied with our current level of preparedness as this is a continuing process.

The threat of agroterrorism is real. From recent events, we know there are forces that are seeking to harm America in any possible manner, and that our agriculture is particularly vulnerable. We know that those who seek to harm us constantly change their tactics. We can not overlook threats to agriculture and our food supply.

In 2002, a group of local committed agriculture leaders joined our community's first responders to develop a comprehensive plan in response to threats of terrorism. This group of leaders recognized the importance of preventing an attack on our economic base. This coalition continues to assess any animal and public health issues that pose a threat to our community.

The Ford County Sheriff's Office, The Kansas Bureau of Investigation (KBI) and the National Agricultural Biosecurity Center (NABC) at Kansas State University recently completed a two-year research project that was sponsored by the National Institute of Justice (NIJ). Previous writings and research identified the dire consequences of agroterrorism, but information related to law enforcement's role and responsibilities were virtually non-existent. This project establishes a base line for law enforcement to better understand the livestock industry and define its role in working together in the common cause of prevention. Further research is required to answer many of the unanswered questions related to this topic.

During the research project, several proactive initiatives were developed for law enforcement to specifically protect agriculture from criminal threats, including acts of terrorism. Local, state, and federal agencies, including the USDA and FBI, and industry participated in these the research activities.

The overall conclusion of this research project centered on the fact that terrorism, regardless of its form or origin, is a local crime and preventive initiates should be developed by local law enforcement in partnership with the livestock industry. Federal funding would be necessary for the implementation of such measures.

Recently, a consortium of state and local animal health, law enforcement, emergency management and academia officials met in Kansas City to discuss strategies in prevention and emergency response issues related to agroterrorism. Representatives from South and North Dakota, Nebraska, Kansas, Oklahoma, Missouri, Colorado and Iowa were present for this important planning session with the overall goal of sharing information and developing strategies that will work beyond state boundaries.

AGROGUARD is a community policing strategy with the goal of bringing Sheriff's and industry leaders together to encourage reporting of and educating front line industry personnel in suspicious activity. Because of the inter-dependence of the industry, this program reaches across

all facets of ag from pre-harvest to post-harvest stakeholders. Many states have shown interest in this concept developed by front line industry personnel in conjunction with law enforcement.

As you may be aware, the Kansas City Field Office of the FBI and the Heart of America Joint Terrorism Task Force recently hosted the 1st annual International Symposium on Agroterrorism. This symposium brought together stakeholders from across the world. A step towards a global initiative on preventing and responding to agroterrorism may have been taken with this important endeavor.

Across the country, planning activities such as field exercises, other training, and communication is occurring. These food chain homeland security efforts must continue with a high degree of urgency. Further, because of the potential consequences associated with an interruption in the food supply, we can not become complacent. Most importantly all communities must understand that they are not immune from such an event.

Local first response agencies are far better equipped to respond to a weapon of mass destruction event because of funding from the Office of Domestic Preparedness. Agencies, who just a few years ago could not offer their personnel protective equipment, can now do so.

In my perspective, the importance of intelligence information being forwarded from the ground up and from the top down is critical. The local deputy sheriff responding to a report of suspicious activity forwarded by an alert industry professional is equally likely to identify and prevent agroterrorism as is the development of intelligence information at the national or international level. Lacking too, the industry must realize the importance of reporting such activity and being an equal partner in protecting itself.

In closing, in 2002, I testified before a Congressional Field Hearing at Abilene, Kansas. Significant progress has been made since that hearing, but there are many threats and challenges that have yet to be addressed. In my opinion, the costs of response are far too high and our focus must be on prevention. From the most simplistic initiatives of preventive policing to the most complex of disease surveillance and food safety technology, the need for prevention can not be overstated. Federal grants and homeland security funding must be available to promote local preventive initiatives, research, and technology to protect against acts of agroterrorism. To eliminate confusion, miscommunication and redundancy, it is essential that a national homeland security strategy addressing the threats of agroterrorism be developed and coordinated.

It has been an honor for me to represent local law enforcement in presenting this testimony. Thank you and I will try to answer any questions you may have.

Written Testimony

The threat of Agroterrorism is real! Understanding this, many rural communities across the nation have assessed their critical infrastructure and have found how reliant they are on agriculture. They have also discovered the unique challenges associated with protecting the food chain. Because of its diversity, the agriculture industry differs greatly from most other industry. Thus a simple and singular plan in the preparation for terrorism is not applicable. A focused regional, if not local, effort at understanding the particular facets of the industry that impact the individual community is required for agroterrorism prevention and response planning. More importantly, a national strategy must be developed to eliminate confusion, redundancy and miscommunications. To accomplish this, partnerships between industry, all of law enforcement, and other first responders must be forged and plans developed specific to the community. Efforts in prevention, including preventative policing, animal health surveillance, and applicable technology must be equally emphasized.

My perspective is that of a local law enforcement officer from the heartland of the country. In our community the beef industry drives the economy. Millions of animals are grown, housed in feed yards, and processed to meet the demands for beef products across the country and the world. Any terrorism event could have far reaching implications from unemployment, eradication and other logistical costs to disruption of the national food supply, and global trade sanctions.

Kansas is highly reliant upon agriculture. As a result, we have been motivated to protect our economic base by developing strong partnerships between all law enforcement and agriculture, particularly the livestock industry. We have made progress in developing preventive measures as well as an emergency response plan. However, this continues to be "work in progress" as much work must be done in the future to protect this nation's food supply from the threat of terrorism.

The beef animal industry is highly efficient. To meet the demands for beef products throughout the United States and the world, it has evolved into a 'non-stop operation' that requires constant, uninterrupted movement of live animals, feed supplies and finished product. "Agromovement" may represent the greatest vulnerability to the industry in preventing, planning for and responding to an agroterrorism event.

Agromovement can best be defined as the continuous cycle of movement required in farm to fork food production, including all aspects of animal transportation to finished products destined for distribution and consumption throughout the world. Each facet, beef, swine, poultry and even fish require some structure in movement. According to the National Agriculture Statistical Survey (NASS), the agriculture industry generates about 1.5 trillion dollars in economic impact in the United States each year. The continued effective movement of pre and post harvest food products is probably the most basic requirement driving this economy. Additionally, there is a specific process of movement related to grain production that directly affects livestock production. This varies region to region based upon the particular feed requirements for livestock.

Grain products are a vital part of this cycle. Locally, in area's where there is a high concentration of livestock, most grain, especially corn and sorghum, are moved to the feeder facilities. Movement to terminals and to export by truck and rail does occur in these areas. Where less livestock are housed the amount of grain products destined for food production including products like cereals and bread is increased. Of concern in grain transportation is the opportunity for terrorist organizations to introduce a chemical or other agent into a load of grain product destined for human or animal consumption.

Transportation represents the greatest concern in livestock disease management. Live animals are transported on a daily basis to meet production requirements. Although most are hauled by the producer or by local contract carriers, there is substantial movement from state to state. In the case of local movement by producers, there is some ability, with time, to trace a vehicle that may have hauled diseased animals. Considering that contract haulers may move animals from one state to another and then back haul to yet another state represents a significant challenge in not only disease management, but in a terrorism event, law enforcement's ability to find and secure a potential crime scene, interview the driver, and prevent the vehicle from traveling, thus spreading the disease. Worse is the fact that incubation periods of highly contagious diseases may be days or even a week or more, thus accounting for a particular trucks movement for that period may be difficult at best. The National Animal Identification System (NAIS), if mandatory, may mitigate some of these problems.

According to many health officials, the greatest threat to the animal industry is the introduction of a biological agent, of which the most feared is probably Foot and Mouth Disease (FMD). This highly contagious disease affects cloven hoofed animals, may be transmitted in aerosol form, is viable in the environment, and readily available in many countries throughout the world. There is little human health risk when handling the virus and little technical 'know how' would be required to introduce the virus into an otherwise healthy livestock population. Considering agromovement, an inadequate response and the potential spread of this highly contagious disease would surely devastate the industry.

The face of terrorism as it relates to agriculture does not only look like that of bin Laden or al-Zarqawi. In fact, some industry professionals deem domestic groups, including anarchists and animal rights groups, a significant threat. Perhaps overlooked, disgruntled employees driven to harm an employer pose an equally real threat. Any of these groups may be motivated by the ability to significantly hamper the U.S. economy and create panic within the public in the sense of an unsafe food supply. A wide scale attack, orchestrated by any of these groups will simply over-burden and likely break the best of response mechanisms.

Agroterrorism, because of the potential impact can not be singly considered a local, state, or federal issue. This issue will require that all resources --- at all levels of government and industry --- join together in a coordinated and logical planning approach. Local level response planning efforts specific to the local industry coordinates prevention, response and resource coordination between all levels of government and the industry. These plans coordinated with State and Federal response plans including the National Interagency Incident Management Strategy and the Incident Command System are the basis for a national strategy. Homeland Security Presidential Directive #9 has given clear direction in protecting the food supply. It is important that a national strategy be developed communicated and coordinated to reduce confusion, miscommunication, and redundancy.

State level response plans for foreign animal disease events have been in existence for a number of years. Although there is some variation in these plans between states, most are based upon the same key points. In general, reporting, sampling, containment of the disease, cleaning and disinfesting of equipment and personnel, euthanasia and burial of diseased animals as required, and recovery, which may include sentinel programs and vaccination.

Duties of responders in an event fall upon a combination of federal, state and local agencies. An effective response requires that local first responders have some level of related emergency planning in place. The reason, a wide scale event will quickly require local communities to request considerable state and federal resources. Secondly, a delay in response to subsequent events at the local level will likely perpetuate it causing even greater reliance upon already taxed resources.

The concept of organizing county or regional level response teams to deal with these issues in the early hours (12-24) is crucial. For example, a state veterinarian or local practitioner once called to a

location to examine sick animals can have resources, identified by the county team at hand. Intended to manage local consequences, these teams could alleviate some of the problems caused by geography and the increased time in standing up state and federal resources and quarantine and stop movement coordination across state borders. The importance of having locally experienced industry professionals involved in consequence management can not be ignored.

The local impact of this event requires planning a response, not only for the industry and other agencies, but especially law enforcement. To understand what the requirements of law enforcement are, the response of the community as a whole must be defined in some detail. Conceptually, a response plan that is inclusive of key industry personnel offers great potential in adequately identifying resources and consequence management in support of law enforcement, public health and other first response agencies. The role of law enforcement will be dependent upon 3 factors: 1) the footprint of the industry; 2) the size of the law enforcement agency, and 3) the structure of the law enforcement agencies within the state, e.g. State Police, Highway Patrol, Bureau of Investigation.

Because of the lack of understanding the potential role of law enforcement, the National Institute of Justice funded research in this area. This project, ***Defining the Role of Law Enforcement in Agroterrorism*** was completed in July 2005 by partners at the Ford County Sheriff's Office, the Kansas Bureau of Investigation, and the National Agricultural Bio-security Center at Kansas State University and more clearly defines those roles. The findings of this research indicate law enforcement has roles in prevention such as identifying threats to the local agricultural industry, conducting vulnerability assessments of potential local agricultural targets, and developing a community policing strategy for the local livestock industry. In emergency response, law enforcement must carry out crime scene management including tissue collection from infected animals, evidence collection from the affected premises, and suspect development. In addition, law enforcement should be prepared to assist in any quarantine and stop movement plans ordered by animal health officials, conduct a full-scale criminal investigation to identify/apprehend/prosecute suspects, and resolve conflicts in the community such as civil unrest, breakdown of basic services, emotional stress, and potential public health issues. Additionally, as part of this project, several initiatives were undertaken. These initiates included:

- Introduction of a community policing program termed *Agro*Guard*;
- Development of regional response teams (KBI special agents and KAHD veterinarians) throughout the state of Kansas; and
- Training for local interdiction officers on un-inspected food products being smuggled into Kansas.

Since testifying at the Congressional Field Hearing held in Abilene Kansas on August 20th, 2002, I am happy to report that planning and training initiatives have made progress. An important component of first responder training is participation in simulation exercises. These field exercises offer the participants an opportunity to better understand their roles in an emergency. Equally important, some level of stress arises from hands-on problem solving in real time. In the case of a simulated agroterrorism event, first responders are provided the opportunity to work closely with industry professionals and identify technology, statutory, and policy/procedure flaws that could hamper an actual response. Additionally, the problems first responders deem insurmountable may be resolved easily by the industry and vice-versa. When developed and conducted effectively, these field exercises provide participants with the necessary knowledge to plan for emergency situations. Likewise, it provides first responders with an opportunity to build a relationship with peers and industry professionals.

A number of exercises have been completed across the country. As part of the NIJ project, two simulation exercises were developed and evaluated. The first, *Sudden Impact* took place in Dodge City,

KS. on January 20th, 2004. Due to the strong agriculture industry presence in western Kansas, officials in Ford County continue to play a key leadership role in developing a dynamic preparedness plan for an agroterrorism attack, specifically an intentionally-introduced foreign animal disease (FAD). Through the FAD sub-committee of our Local Emergency Planning Committee (LEPC), we have established an integrated emergency plan that serves as a role model throughout the state of Kansas. This sub-committee is a partnership between local government and key representatives from the livestock industry. This partnership incorporates expertise from all disciplines including veterinarians, feed yard managers, ranchers, transportation experts, animal health professionals, meat processors, law enforcement and other first response agencies to form a diverse team in combating the threat of agroterrorism in western Kansas.

The purpose of exercise *Sudden Impact* was to provide an advanced-level of testing for all phases of the emergency plan established by the Ford County FAD Committee. Because the emergency plan had undergone an initial exercise in October, 2002, *Sudden Impact* was designed to challenge changes in the plan, primarily in the areas of coordination and communication. Objectives for this exercise included: (a) assess the effectiveness of a public health quarantine; (b) identify issues for law enforcement in implementing a human quarantine; (c) identify concurrent issues evolving from a zoonotic animal disease; and (d) observe improvements in the emergency operations center (EOC) from the previous (Oct. 2002) exercise.

From this exercise it was realized that foreign animal disease emergencies will create an immediate reaction by the public and necessitate a continuous flow of up-to-date and accurate information. Public education concerning the impact of a foreign animal disease should be treated as a priority. Law enforcement officials should review the number of officers that would be available to enforcement any type of emergency quarantine, and develop additional manpower resources, such as: reserve officers, conversion of non-commissioned officers, trained volunteers, etc. It is imperative that local law enforcement have immediate access to the identity of suspects and organizations that pose a threat to their community. A central database, similar to KsLEIN (Kansas Law Enforcement Intelligence Network), should be amended to specifically include suspects and organizations involved in possible agro-terrorism threats. This database should be connected to the federal terrorist tracking systems, such as the FBI's Terrorist Screening Center (TSC) and the Terrorist Threat Integration Center (TTIC) [now the National Counter Terrorism Center (NCTC)] in Washington, D.C. The Kansas Animal Health Department (KAHD) and the Kansas Bureau of Investigation (KBI) should establish Regional Response Teams, comprised of veterinarians and special agents, to train together and respond to any foreign animal disease at the "highly likely" level. This partnership would combine animal health and criminal investigation expertise.

Based on these findings, a second exercise titled, *Endangered Species,* was developed to test law enforcement's capacity to receive and analysis threat information and take preventive action. Since public events are likely targets of terrorism, a scenario was designed to test participants in a state fair setting. The primary goal of *Endangered Species* was to assess the connectivity of public health, animal health, and law enforcement in an emerging terrorist threat. Agency coordination was a key factor in recognizing the threat and implementing necessary safeguards. This exercise was conducted in Reno County Kansas in October of 2004.

When preparing for an emergency response for an outbreak of a foreign animal disease, *prevention* is a primary consideration. P*reventative* measures to protect agriculture, particularly the livestock industry, from an act of agroterrorism, reduce the potential economic impact to the community. Further, it would eliminate the need to allocate resources required for response.

Understanding the critical nature of information sharing is paramount to successful intervention. Industry leaders should develop an infrastructure that facilitates information sharing with law enforcement. Front line employees should be trained to recognize vulnerabilities, threats to the industry, the nature of suspicious activity, and reporting procedures. It is important that law enforcement be notified to investigate any suspicious activity. Once received, law enforcement can then begin the process of evaluating and converting threat information into intelligence, thereby providing first responders an opportunity to prevent acts of terrorism. With actionable intelligence, industry officials can then also place additional safeguards and increase awareness in and around their facility.

Intelligence databases and analytical centers are now in place to track suspects, activist or extremist groups, and suspicious activities to alert local authorities to potential threats related to terrorism. The purpose of this network is to provide law enforcement with an advanced warning for appropriate action in dealing with threats, including acts of agroterrorism.

From our perspective, information sharing between local, state, and federal agencies has improved, but further improvement can be made. The importance of intelligence information being forwarded from the ground up and from the top down is critical. The local deputy sheriff responding to a report of suspicious activity forwarded by an alert industry professional is equally likely to identify and prevent agroterrorism as is the development of intelligence information at the national or international level. Therefore emphasis on sharing information at all levels must be maintained. The industry must realize the importance of reporting such activity and being an equal partner in protecting itself.

Agro*Guard is a community policing program. The ultimate goal of the program is to build a partnership between local law enforcement and the agriculture industry – an alliance that has likely never been forged before. Best described as Neighborhood Watch for the agriculture industry, the program is designed to educate front line employees and stakeholders in the principles of identifying and reporting suspicious events to police. Understanding the threat, the vulnerabilities, what exactly their role is, how to report suspicious activity and how to most appropriately manage the risk will give stakeholders the ability to be an active partner protecting the nation's food supply. The significant communication gap that exists between law enforcement and the agriculture industry must be closed to increase the chances of prevention. When this occurs, the above mentioned early warning for law enforcement occurs, thus offering the chance for intervention and prevention. The research partners along with the Kansas Animal Health Department and Department of Agriculture support and promote the program.

In addition to field exercises, a number of initiatives geared towards training have been held. The FBI Kansas City Field Office and the Heart of America Joint Terrorism Task Force recently hosted the International Symposium on Agroterrorism (ISA). Attended by some 800 participants from around the world, this venue offered participants a look at the roles of different agencies in the prevention and response to agroterrorism. What's more, it may have laid the groundwork for an international prevention approach.

Several other initiatives evolved from the NIJ project. In May of 2005, a consortium of state and local animal health, law enforcement, emergency management and academia officials met in Kansas City to discuss strategies in prevention and response issues that will clearly know no state borders. Members from the Dakota's, Nebraska, Kansas, Oklahoma, Missouri, Colorado and Iowa were present for this important planning initiative. Most importantly, the ability to manage movement of agricultural products in a terrorism event was identified as being critical to success. A separate but partnering multi-state ag security coalition currently is conducting research and furthering strategies for animal health, ag and emergency management.

Regional Response Teams first identified in *Sudden Impact* are now in place in Kansas. The importance of these teams can not be understated as they insure the proper collection of evidence for the purpose of prosecution. These teams, which are comprised of state investigators and animal health officials, respond to investigate suspicious signs and symptoms in the livestock population. Previously carried out only by animal health officials, this innovative partnership puts law enforcement eyes on a potential terrorism event from the onset leading to more efficient resource allocation and the above mentioned crime scene management and evidence collection. Law enforcement now works closely with veterinarians from the Kansas Animal Health Department and the Kansas Livestock Commissioner on a routine basis. In the past, this would only have occurred "after-the-fact" when a major theft had been reported or some crisis had taken place

Local and state first response agencies are far better equipped to respond to a weapon of mass destruction event because of funding from the Office of Domestic Preparedness. Agencies who just a few years ago could not offer their personnel protective equipment can now do so. Training and education efforts through ODP are now offered in different locations throughout the country. More can be done. The identification of more equipment specific to agroterrorism response is needed and then made available to local and state agencies. Because of the diversity of the industry, training initiatives for first responders must be specific to each community emphasizing the predominant facets of agriculture present there. Further the need for funding additional street level officers is ever present and programs that have allowed for this must somehow be maintained.

Overall we have made progress, but have a long way to go. The reality is that some industry professionals are more likely than others to participate in local planning initiatives. Also, as unfortunate as it is, some Sheriffs have been reluctant to embrace agroterrorism as a priority for their department even when their local community has an agriculture-based economy.

Law enforcement and agriculture must develop local partnerships and establish preventive strategies. Further research must be conducted related to law enforcement and its role in agroterrorism. The diversity of our agricultural economy and food supply leaves many unanswered questions as to how law enforcement may interface with the industry in all facets. Some incentive must be directed at agriculture to increase its willingness to place more safeguards to protect its assets from within, rather than simply relying on state and federal government.

We recognize that in the end an agroterrorism event will probably look much different than a natural occurrence or accidental introduction. We should carefully evaluate our national response strategy to insure that is appropriate for terrorism and not just cases of accidental introduction or natural occurrences. It would be unacceptable to think that terrorists would fail at initiating a wide scale event if it were their intent. This in itself should motivate all stakeholders, public and private, to unite and address this serious threat.

The key to protecting against acts of agroterrorism is the development of *new* partnerships and *new* thinking in terms of preventive initiatives. We must join forces, share information, and most importantly, work together as equals in developing prevention and emergency response strategies.

Testimony of
Mark J. Cheviron
Corporate Vice President
Director Corporate Security & Services
Archer Daniels Midland Company

before the
Senate Committee on Agriculture, Nutrition and Forestry

July 20, 2005

Good morning, Mr. Chairman and honorable Members of the Committee. I am Mark Cheviron, Corporate Vice President and Director of Corporate Security for the Archer Daniels Midland Company. Archer Daniels Midland, or ADM, is an integrated agricultural processor. We buy farm products – corn, soybeans, wheat, oats, cocoa - and produce food ingredients like edible vegetable oils, flour, animal feeds, and renewable fuels along with other industrial products. In order to produce and sell more than $36 billion of products each year, we rely on over 250 processing plants, more than 500 grain elevators, and a workforce of nearly 26,000 people worldwide. Keeping our facilities and our people safe is my job, a position I have held for over 25 years.

The threats I confront have changed over this period. While I used to worry primarily about theft, fraud, vandalism and workplace violence, I now must also be concerned about bioterrorism. I am glad that you share this concern.

America has made progress in hardening our defenses of traditional terrorist targets – military bases, government facilities, and commercial air travel. Only recently has our country turned its attention to better protecting crops, livestock and the other products, which flow from our farm communities. As President Bush has said, "Agriculture ranks among the most crucial of our nation's industries: yet its reliability and productivity are often taken for granted."

Protecting ADM from agroterrorism is my responsibility – but one that I cannot do alone. Business and government must work in partnership and with each day this partnership strengthens. We are grateful for the assistance we have received through collaboration with the organizations represented on today's first panel as well as with local authorities. We are moving in the right direction but more can be done. Let me outline four areas in which I see room for improvement:

1) Agroterrorism is an international problem infinitely more comprehensive than any one company or industry. In order to be better prepared, the private sector needs better access to the counter-terrorism units of the federal government, which have the expertise to identify emerging threats. I know the most effective way to mitigate these risks for ADM, but I can only address those risks of which I am aware. Federal counter-terrorism experts can help the private sector understand potential threats, which will guide our development of effective/efficient countermeasures based on those risks. We can enhance

our overall level of preparedness by working together and maximizing our collective strengths.

2) A bioterrorist attack on our food supply can have a significant effect even when the amount of contaminant is small. The best response discovers and isolates a contaminant before it permeates and travels throughout the food chain. Today, the technology for detecting these threats is inadequate. Again, public/private partnering is essential. The public sector must take the lead to insure the development of detection technology that works seamlessly from field to fork. The private sector can help, as a knowledgeable partner, at each link of this chain. But the government must commit the funds – which is likely to be considerable - and insure that detection activities can be integrated throughout the food supply chain. Working in partnership we can identify attacks quickly and isolate their effects.

3) Certain food security regulations, which are knee-jerk, theoretical and uncoordinated, are counterproductive. Everybody agrees that agroterrorism is a complex problem, but regulatory approaches that proscribe "across the board" infrastructure changes or "one size fits all" procedural requirements are doomed to fail. Some businesses will be required to spend needlessly to meet mandates that neither efficiently nor effectively mitigate the real risks they face. Others will be able to comply with "checklist" regulations while leaving real risks unaddressed.

I am not opposed to practical regulations that address true risks – the private sector wants to be sure that these regulations actually work and strengthen our defenses. We can accomplish this by working together. The public sector's role is to provide funding for more focused research before a regulation is written. The private sector's role is to identify functional systems, which are suitable for use in industrial processes and operations.

4) In order to win this war on terrorism, we need to enhance the exchange of information and expertise between the public and private sectors. This is harder than it sounds. On the private sector side, we encounter difficulties when sharing trade secret or proprietary information with the government. We have no easy avenue of recovery when this information is released inappropriately and that causes hesitation. On the public side, there are just too many "clearances" needed – which limits access to the information and creates too many opportunities for unauthorized disclosure. We need to think through what restrictions are absolutely necessary to protect businesses and to protect sensitive government information and then devise a system that works for all interested parties. Information sharing is key – this seems obvious, but in reality it means that timely and accurate information must flow both ways.

From industry, we are the street level counter-surveillance, able to identify suspicious activity rapidly. From government, you are the experts on emerging threats. Working jointly we can review this threat information and determine what level of alert is appropriate. This gives the private sector the tools to take the necessary steps to protect our assets.

Finally, we would welcome the designation of a single point of contact in the government for reporting suspicious activity. No time should be lost trying to determine who should be called when suspicions are raised.

Thank you Mister Chairman and honorable Members of the Committee for allowing me to speak today. Agricultural processing is ADM's business. Insuring the reliability and safety of our nation's food supply is everyone's business. We are proud to be your partner in the war against terrorism.

This concludes my testimony.

DOCUMENTS SUBMITTED FOR THE RECORD

JULY 21, 2005

STATEMENT OF SENATOR TOM HARKIN (RANKING DEMOCRATIC MEMBER)
COMMITTEE ON AGRICULTURE, NUTRITION AND FORESTRY
HEARING ON BIOSECURITY AND AGROTERRORISM THREATS
JULY 20, 2005

Thank you, Mr. Chairman, for calling this hearing to review agricultural biosecurity and our nation's efforts to address the threat of agroterrorism. Because the food and agriculture sector is such a vital part of our national economy, outbreaks of animal or plant diseases from either unintentional or intentional causes have the potential to cause tremendous economic damage and disruption. Some diseases – avian influenza, for example – are capable of infecting humans and causing very serious illness and loss of life. A less tangible, but potentially even more unsettling, threat is rooted in the fact that Americans have for so long enjoyed an abundant and economical food supply. Serious shortages of food or disruptions in supplies – or incidents of intentional contamination – would strike at the heart of the food security we take for granted. Terrorists could hardly dream of a more effective way to cause chaos or even outright panic in America.

Today's hearing will help us better understand what the government departments and agencies responsible for biosecurity and guarding against agroterrorism have accomplished – and what must still be done. It would be hard to overstate the magnitude or gravity of these responsibilities. Most important is doing all we can to prevent and head off these threats. But we also have to be prepared to respond quickly to an incident, to contain and limit disease outbreaks or other threats, and then to recover and repair the damage. We must carefully allocate resources and close gaps. I want to thank Dr. James Roth, from Iowa State University's Center for Food Security and Public Health, and all of the other witnesses for joining us to testify today.

As our witness list reflects, several departments and agencies share responsibility for preventing and responding to biosecurity and agroterrorism threats. I commend them for the steps they have taken. However, we have a very long way to go to address these biosecurity and agroterrorism threats adequately. For example, in March of this year the Government Accountability Office found that while progress has been made, significant and troubling gaps and shortcomings persist. We are playing a catch-up game with no time to waste.

We also need stronger support and tools for first responders in agriculture, more research and training of professionals, better rapid diagnostic tests and adequate supplies of ready-to-use vaccines. Stronger coordination and communication among all of the federal departments and agencies and with state and local authorities is critical. In particular, there are too many unresolved issues in the division of responsibility and allocation of resources between USDA and the Department of Homeland Security – notably in protecting our borders. Iowa is among the 11 states that formed the Multi-State Partnership for Security in Agriculture to help make up for federal shortcomings. This partnership deserves more funding, support and cooperation from DHS and USDA. In short, biosecurity and agroterrorism threats to our nation's food and agriculture are very serious, but too little federal funding, personnel and attention are being devoted to the challenge. I urge the administration to work with us in Congress to remedy these shortcomings in our preparedness. There is absolutely no time to waste.

Statement of Senator Thad Cochran
Senate Agriculture, Nutrition, and Forestry Committee
Wednesday, July 20, 2005, 10 am, Russell 328A

Mr. Chairman, I look forward to working with you and the other members of the Committee as we examine the unique convergence of responsibilities among several federal departments, including Homeland Security, Agriculture, and Health and Human Services on the issue of bioterrorism.

Today's panel of witnesses can provide important perspectives on the security of our nation's food supply and our ability to prepare for attacks against it.

Research is an important component of this effort. I am pleased that the Department of Homeland Security is planning to build the National Bio and Agrodefense Facility. This will have important benefits for the Department of Agriculture and other agencies as well. The efforts of Dr. McCarthy and Mr. Conner to work across department jurisdictions on this effort will be important to the success of this project.

It is important to note that the work of the Agricultural Research Services and the Food and Drug Administration in coordinating with university researchers has provided important results as well.

Agricultural terrorism could have devastating affects on the economy of my state of Mississippi. In Mississippi, agriculture is a $5.5 billion industry with an economic impact of $24 billion each year. Protecting the safety of our food supply is a very high priority.

Please be assured that we are committed to giving the federal departments and agencies the resources that are needed to fulfill these responsibilities. We will continue to look to you for insight to help us focus our resources on the programs and projects which will best serve our national interest.

I look forward to hearing from each of you today. Thank you.

STATEMENT OF
MARY UPCHURCH KRUGER
DIRECTOR, OFFICE OF HOMELAND SECURITY
OFFICE OF THE ADMINISTRATOR
BEFORE THE U.S. SENATE COMMITTEE ON
AGRICULTURE, NUTRITION, AND FORESTRY
JULY 20, 2005

Introduction

Thank you for the opportunity to provide written statement for the record concerning the role of the Environmental Protection Agency (EPA) in preparing for, and building the capability to respond to potential acts of agroterrorism. EPA has a focused and important role in responding to agroterrorism and works closely with other agencies under the umbrella of the National Response Plan and the Food and Agriculture Government Coordination Committee to ensure the U.S. agricultural sector and food supply are protected from chemical and biological threats.

As part of its basic mission to protect human health and the environment, EPA has a number of core programs important to preventing and responding to agriculture and food incidents. Specifically, EPA has relevant authority and responsibilities in the areas of pesticide regulation, waste management and disposal, and water quality. In addition, the Agency has enhanced its collaboration with other federal agencies and state and local authorities on agroterrorism issues. EPA is an active participant in homeland security activities, providing technical and regulatory expertise. My statement outlines EPA's food and agriculture-related authorities and activities and provides an example of how the Agency responds to potential threats.

I. Overview of EPA's core legislative/regulatory programs to combat agroterrorism

PESTICIDES

EPA's Office of Prevention, Pesticides, and Toxic Substances (OPPTS) evaluates pesticide safety and makes regulatory decisions designed to protect human health, the environment, and the food and feed supply. This is important in the homeland security context because pesticides are used to treat and decontaminate agriculture, livestock and food facilities from crop, livestock, animal diseases and pathogens.

The Office of Pesticide Programs is charged with regulating pesticides under two primary laws – the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Under FIFRA, EPA is responsible for evaluating and registering pesticides prior to their marketing in the United States so that effective means for pest control are available while meeting the FIFRA safety standard. EPA must ensure that the pesticide, when used according to label directions, will not pose an unreasonable risk of harm to human health or the environment. In addition, EPA must also ensure the pesticide is efficacious as claimed. For example, someone who has

decided to landfill diseased animals/waste as a result of an agroterrorism attack would be directed to the appropriate state agency to ensure selected municipal landfills are in compliance with 40 CFR Part 258. This is particularly important in the context of a terrorist attack which would necessitate the effective inactivation of pathogens on surfaces. Where pesticides are used on food or feed crops, FFDCA requires that EPA set tolerances (maximum pesticide residue levels) for the amount of the pesticide that can legally remain in or on foods for human consumption and feeds for livestock.

EPA's emergency exemption process is designed to quickly and effectively ameliorate pest emergencies brought on by unpredictable and severe environmental circumstances such as an intentional contamination, extreme weather, or the development of resistance to available pesticides. Under an emergency exemption process, outlined in Section 18 of FIFRA, other federal agencies or an authorized state official may request that EPA allow the use of an unregistered active ingredient or an additional use for a registered pesticide to respond to emergency conditions.

Additionally, as with soybean rust, emergency exemptions may be granted to respond to new and significant pests and invasive species that could threaten the food supply. Finally, in the case of the anthrax attacks of October 2001, EPA developed a highly expedited process for issuing crisis exemptions to permit the emergency use of antimicrobial products for inactivation of *Bacillus anthracis* spores at numerous contaminated sites such as the Hart Senate Office Building, U.S. Postal Service processing and distribution centers, and other federal and private buildings.

The underpinnings of full registrations and emergency registrations are scientific data and risk assessments involving dietary exposure (where food or feed uses are involved), occupational exposure, ecological and environmental impacts, including effectiveness data for pesticides for which efficacy claims are made. To cover pesticide residues in food or feed crops EPA must establish tolerances (maximum allowable residue levels). This ensures that treated food or feed crops are safe to be consumed and can be legally marketed in national and international commerce, including residues resulting from emergency uses of pesticide products under Section 18.

In addition, OPPTS has used its expertise and experience with antimicrobial pesticide products for homeland security purposes. For example, following the 2001 anthrax contaminations, EPA's Microbiology Laboratory in Ft. Meade, Maryland conducted efficacy tests on several liquid decontaminants to determine whether they met the agency's efficacy performance standard. The Agency worked in collaboration with the Centers for Disease Control and Prevention (CDC) to determine which antimicrobial products should be tested. EPA is also working with CDC to determine which pathogens pose the greatest potential threat, so products can be tested for use against those microorganisms.

OTHER PROGRAMS

EPA is actively participating in several internal and external workgroups and committees to facilitate collaboration and information sharing among the government's laboratories. For example, EPA contributes actively to the inter-agency Integrated Consortium of Lab Networks. The Agency has also established formal links with the Department of Homeland Security's food and agricultural research centers.

EPA's Office of Solid Waste and Emergency Response implements federal laws and regulations to ensure safe management and disposal of hazardous and non-hazardous solid waste primarily under the authority of the Resource Conservation and Recovery Act (RCRA). An example of how this authority might be used would be to direct someone landfilling diseased animals/waste in response to an agroterrorism attack. The state agency would ensure the diseased animals/wastes are disposed of in municipal landfills that meet specific criteria. That is, municipal landfills compliant with the federal criteria in 40 CFR Part 258.

The National Response Plan coordinates national resources and activities during incidents of national significance. USDA has lead responsibility for agricultural incidents under ESF #11, but EPA, in cooperation with several other federal agencies, will provide needed support consistent with the respective missions.

Under EPA's Clean Water Act authorities, EPA could assist in monitoring local water bodies to minimize potential effects of mass disposal of animal carcasses that may arise from an agroterrorism attack. EPA could also have a role in overseeing water quality monitoring and environmental sampling under an Incident Command Structure.

II. Overview of HSPD-9: Additional Roles and Responsibilities for EPA in Protecting Food and Agriculture against Agroterrorism

HSPD-9: Defense of United States Agriculture and Food establishes national policy to defend the agriculture and food system against terrorist attacks, major disasters which occur naturally, are unintentionally introduced, or are intentionally delivered by man, and other emergencies. This Directive is aimed at incidents where the primary impact is on agriculture and food infrastructure. HSPD-9 calls for recovery systems able to stabilize agricultural production and food supplies, including removal and disposal of contaminated agriculture and food products or infected plants and animals and decontamination of premises. In addition, it calls for pesticide control measures to prevent, slow, or stop the spread of a high-consequence plant disease. It also calls for the creation of a series of more specific plans and strategies.

In support of HSPD-9, the White House Homeland Security Council (HSC) specifically tasked EPA to coordinate with the U.S. Departments of Agriculture (USDA), Health and Human Services (HHS), Defense (DOD), and Homeland Security (DHS) to develop a joint concept of operations (CONOPS) for coordinated decontamination and disposal efforts for a potential chemical or biological contamination event in either food or agricultural systems. This document, in draft, describes the general federal roles and responsibilities for decontamination and disposal in response to such an event. It is

consistent with the NRP and is intended to clarify and document existing relationships among the federal departments and agencies. Federal roles and responsibilities are described for incidents at three levels of magnitude involving chemical and/or biological agents. The focus is on large-scale emergencies or intentional contamination incidents of any size (i.e., non-routine incidents). EPA anticipates submitting the document to the HSC in August 2005.

In support of HSPD-9 Section 18(b), EPA is actively participating in developing the National Plant Disease Recovery System (NPDRS). USDA established NPDRS with a goal of identifying one or more efficacious pesticide products for each of the plant pests identified as "select agents". To that end, we have been actively collaborating with USDA by providing them potential pesticides for each of their identified select agents. USDA has formed an NPDRS Committee, as required by HSPD-9, to identify critical characteristics of the select plant agents of high consequence and identify suitable prevention and control methods, including chemical, non-chemical, and development of resistant seed varieties to sustain production for economically important crops. For each disease, the NPDRS Committee will develop response plans, including a strategy for detection and monitoring of the plant disease, effective communications, and rapid response (chemical controls) and longer-term response (development of crop varieties with disease resistance) to control and manage the disease. EPA is an active member of the committee, providing technical and regulatory information about potential pesticides for USDA's consideration.

EPA also is a charter member and active participant in the Food and Agriculture Government Coordinating Council established last year by DHS. Other charter members include USDA, FDA, DOD, and key government associations representing state and local governments. The mission of the Council is to coordinate security strategies and activities, policy and communication across government and the industry sector, facilitate research programs, share threat information, and coordinate with the public health sector.

III. Soybean Rust: An Example of HSPD-9 Implementation

EPA's recent experience with soybean rust infestation highlights our involvement in HSPD-9's NPDRS. Years ago it was predicted soybean rust could infect the U.S. Because it is a significant disease that can threaten the food supply, our goal has been to ensure that growers have the necessary tools available before a potential outbreak. We have successfully met that goal. In 2002, EPA engaged in planning for soybean rust by establishing solid lines of communication and relationships with the major stakeholders, primarily USDA, state departments of agriculture, industry, and the soybean grower trade association. These lines of communication and relationships have been facilitated though our contribution in countless conference calls, workshops, and meetings. Further, they allowed us to build our expertise in soybean rust well in advance of an impending outbreak.

As predicted, soybean rust was identified in the U.S. in November 2004. By that time, OPPTS had already approved Section 18 exemptions for 25 states covering three

active ingredients for six end-use pesticide products. Additionally, the OPPTS approved registration actions for four pesticide active ingredients. OPPTS continues to collaborate with USDA, state lead agencies, registrants, and the nation's soybean growers in responding to the discovery of soybean rust. USDA is concerned that many other commercially important legume crops, including peas and beans, will be susceptible to the soybean rust pathogen. USDA and lead agencies in states involved in the production of specialty legumes are working with OPPTS to evaluate the available fungicide tools, and this review is expected to lead to the submission of additional section 18 emergency exemption programs.

EPA met with the National Association of State Departments of Agriculture (NASDA), USDA, American Farm Bureau, and the American Soybean Association (ASA) in December 2004 to discuss the registration status and anticipated supplies of products for growers. The Agency is committed to keeping these lines of communication open as we address this issue.

EPA has worked diligently over the past few years to ensure an adequate variety and supply of pesticide products for growers to utilize in soybean rust control. The Agency is driven to provide these registrations in a timely manner as we understand the significance of safe and effective pesticide products available in light of this potentially devastating pest. In summary, OPPTS currently has registered or granted emergency exemptions for nine pesticide active ingredients for 19 different pesticide products to be used in 32 soybean-producing states.

IV. Additional Legislative Authorities

At this time, EPA finds it unnecessary for additional legislative authorities. We continue to capitalize and fully utilize existing formal and informal relationships with other agencies and councils to ensure adequate and appropriate protections for our agriculture sector and food supply. Further, the Agency continues to explore additional ways of working and collaborating with Congress, our federal, state, and private partners ensuring we take every step to protect the agriculture sector and the food supply from intentional attacks.

V. Conclusion

EPA is working to ensure that U.S. agriculture is provided with the information and tools necessary to prepare for potential agroterrorism events. Working under the umbrella of the National Response Plan, and in collaboration with other federal, state, and private partners, the Agency continues to investigate approaches to protect the agricultural community and the American food supply. The Agency looks forward to continuing this work and welcomes input on this critical topic.

MetaMorphix, Inc.

Prepared Statement of

Edwin Quattlebaum, Ph.D
Chairman, President, and Chief Executive Officer
MetaMorphix, Inc.

Use of DNA Technology to Protect the National Food Supply from Agro-Terrorism

Before the Committee on Agriculture, Nutrition, and Forestry
United States Senate

July 20, 2005

Mr. Chairman, Ranking Member Harkin, and Members of the Committee, thank you for allowing me the opportunity to share my views on ways our nation can improve its measures to guard against agro-terrorism. This is a very important topic and I commend the Committee for its focused attention to this pressing homeland security concern. As President, Chairman, and CEO of MetaMorphix, Inc., a life sciences company dedicated to improving the global food supply through DNA based technology, I would like to offer some insight as to how this technology can be utilized as a tool in the drive toward the development of a secure and safe food supply.

Among the important proposals for protecting the American public from an agro-terrorism incident are measures to protect facilities, development of appropriate countermeasures and improvement of preventative measures at our borders. My focus today, however, will be on another significant aspect of food safety and that is animal and food tracking. In this testimony, I want to speak specifically to the use of DNA in tracking and identifying animals throughout our national food supply system. As you are all aware, in January of 2004, President Bush issued Homeland Security Presidential Directive – 9 (HSPD-9) Within that Directive, the President charged a number of agencies, including USDA, with developing "systems that, as appropriate, track specific animals and plants, as well as specific commodities and food." I believe that such a tracking system is essential to our overall efforts against agro-terrorism and if developed with the right technology, could help to quickly contain an animal disease outbreak with minimal disruption.

Inherent in the current animal production process are a number of vulnerabilities that can be easily exploited by terrorist organizations. For example, livestock are often grown in remote yet expansive locations that are difficult to secure, including open fields throughout the American countryside. Large populations of animals are often found together, making the entire herd susceptible as disease could quickly spread once an infection begins. During the production process, livestock that originate from a number of locations are transported and intermixed, making individual animals difficult to track. These factors coupled with the fear and loss of life that could result make our livestock an attractive target for terrorism It is therefore essential that more be done to track animals and specific food commodities as they move through the food supply process. The ability to pinpoint where in the system a particular animal or commodity was compromised will enable us to take measures to address the problem appropriately. HSPD-9 was absolutely on target to call for the establishment of such a system because reliable intelligence would be very important to containing the spread of an animal disease outbreak.

The recent detection of a cow born and raised in Texas with Bovine Spongiform Encephalopathy (BSE) indicates the importance of being able to track an animal's origin and movement throughout its life and to determine its age, offspring and cohorts. This recent incident also underscores the important role DNA technology can play in making these determinations. A statement by APHIS describing the methods employed to track the infected animal pointed out that "due to the fact that this animal was sampled at the same time as four other animals and parts of the carcass were stored together, **USDA**

made the decision to conduct DNA confirmatory testing before announcing the state of origin...DNA testing has now verified that USDA correctly identified the positive animal" (emphasis added)

Efforts are currently underway at the USDA to develop a National Animal Identification System (NAIS) and I applaud this initiative. At this time, the Department is focused on creating a system that can be put in place that would enable the tracking of livestock. As the system itself takes shape USDA will review specific technologies that could be incorporated into such a regime. Because USDA will ultimately turn to DNA analysis for absolute confirmation in the event of a contamination incident, we suggest that a DNA component be incorporated into the National Animal Identification System from the outset so that the approach to verification is systematic and not *ad hoc.* Using DNA after an outbreak can be extremely time consuming, costly and lead to many dead-ends.

An animal identification program which includes DNA sampling and storage is the only tracking mechanism that will permit the USDA to identify the origins of a specific animal as well as identify parts of the animal that may have been separated from the original. A study conducted in the fall of 2004 under the auspices of the Tri-National Livestock Health and Identification Consortium and the Colorado Livestock Identification and Tracking Project, both of which are coordinated by the Colorado State Veterinarian, demonstrated the strength of adding DNA technology to the identification process. The double-blind study, involving MetaMorphix, Inc., Colorado State University (CSU) and RMS Research Management Systems USA successfully matched 34 cows through DNA samples, alone. In every single DNA test conducted, including matching duplicate blood samples, matching impure blood samples, and matching blood samples to hair samples, the results were the same: **100% accuracy.** Moreover, the results were delivered to the Colorado State Veterinarian in 32 hours, 14 minutes (well within the 48 hour goal set by the NAIS). The outcome of this study has far-reaching implications for the establishment of an effective and meaningful animal ID system in the United States. Not only can animals be tracked quickly using DNA technology but their identification is irrefutable. Furthermore, the technology allows for the expansion of the system to post harvest applications since only a blood sample (as opposed to a live animal) is required to conduct an identity test.

A DNA sample can be collected at the very same moment a Radio Frequency ID (RFID) tag is issued thereby adding only a small, incremental cost to a tagging system. This proposal envisions one tagging operation to fulfill both functions: the animal is tagged with an RFID tag which produces a blood sample to be collected and archived. As animals move to other premises in downstream production a small percentage are re-sampled for audit purposes, and analyzed along with the archived samples from those animals. The DNA profiles that are created from both the archived sample and the new sample are compared to ensure a match. It should be noted that the only time the genotyping (or DNA matching) of the animals is necessary is in the case of a contamination incident. Utilization of DNA-matching technology as a tool to monitor the effectiveness of any animal tracking system provides additional assurance to consumers, as well as international markets, of the safety of the U.S. beef supply.

Another distinguishing feature of a DNA-based program is that an animal's true identity can be determined regardless of whether a tag has been lost, tampered with or switched. In other systems if a tag has been lost or switched, there is no absolute method to confirm the original identity of that particular animal. As a result, the investigation of a disease outbreak may become cumbersome as investigators may track the wrong animal history and are unable to locate herd mates or determine the premises where the contamination occurred.

With a DNA sample, the true identity of that animal is irrefutable and the necessary measures can be taken to contain an outbreak. The animal's history can be confirmed as far back as the farm of origin and tracked as far forward as the consumer's plate. A program based on DNA sampling and storage will allow authorities to obtain information about the movement of an animal over its lifetime within 48 hours. Such a quick response will allow USDA to quickly quarantine any affected animals and recall any tainted meat. The combination of the Department's rapid response and the accuracy of DNA sampling will not only contain the problem, but will also assure the public and U.S. trading partners that the US meat supply is safe.

Further, the needed DNA sampling and storage technology is currently available and could be implemented on a programmatic basis across the country quickly and cost-effectively, without significant disruption to livestock producers. If DNA sampling is linked to the ear-tagging process, whereby the DNA sample is taken from the drop of blood that results during the tagging process, it will require little additional work on the part of ranchers and feedlots.

It is my view that the Senate Agriculture Committee should seriously consider the advantages of using DNA based technology in the animal tracking system currently being developed at the USDA. Using the genetic code to trace animals and food throughout the food production system carries a number of advantages over the sole use of RFID tags. First, it would enable the identification of a specific animal even after harvest. Hence, if an animal disease or pathogen is found in contaminated meat, authorities could trace it back to an individual animal grown at a specific location. That would enable a very targeted response rather than a broad approach that could lead to unnecessary economic disruption and panic. Further, a DNA based system is highly accurate in determining identity. The technology has been verified within the human population as genetic information is routinely used to identify individuals and such characteristics as parental relationships. Additionally, DNA from an animal is identical and unchangeable in every cell, making such a tracking system essentially tamperproof.

Harnessing DNA technology for animal identification will vastly improve our ability to track animals throughout the food supply. This will help in our response to an agro-terrorism event in cases where animal diseases are used as weapons. The system would also be applicable to a natural outbreak of an animal disease, allowing animal health experts to make more informed decisions. In fact, as I already mentioned, recently the USDA used DNA to confirm the identify of a cow infected with BSE. It is important to

note that implementing a DNA based tracking system would not be burdensome as a DNA sample could be taken at the time the animal is tagged.

In conclusion, I urge this committee to work with the USDA to be sure that the most appropriate technology is incorporated into a National Animal ID System. I believe you will find that genetic science, specifically DNA based technology, provides the most accurate and reliable information to identify animals and their food products throughout the food processing system.

Thank you for the opportunity to testify before this Committee. I applaud your efforts and look forward to working with you towards the goal of securing our nation's food supply.

COMPANY SUMMARY

Founded in 1994 and based in Beltsville, MD, MetaMorphix Inc is a life science company discovering and developing products for the animal and human health industries. Drawing on two proprietary technologies, genomics and growth differentiation factors, we are developing products to increase livestock quality and production efficiency, companion animal health and potentially treat human diseases. MMI has developed an innovative system that integrates its unique DNA-based technology with visual/RFID components to enhance animal identification and traceability from the farm to fork.

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For the Office of AGRICULTURE, NUTRITION & FORESTRY for FY (Resolution) 50B
Y-T-D As Of Calendar Month/Year June 2005

Senate Doc. No.	Post Date	Start Date	End Date	Vendor Name	Vendor No	Amount
23.32.39 TELECOM CERTIFIED - CELL/MOB PHO-UNALLOC						
CV050008907	04/12/2005	03/01/2005	03/28/2005	SERGEANT AT ARMS	VN00006347-08	-$497.77
CV050008908	04/12/2005	03/01/2005	03/28/2005	SERGEANT AT ARMS	VN00006347-08	-$313.10
CV050010517	05/09/2005	03/29/2005	04/28/2005	SERGEANT AT ARMS	VN00006347-08	-$314.16
CV050010518	05/09/2005	03/29/2005	04/28/2005	SERGEANT AT ARMS	VN00006347-08	-$113.57
CV050011211	06/09/2005	04/29/2005	05/28/2005	SERGEANT AT ARMS	VN00006347-08	-$370.79
CV050011212	06/09/2005	04/29/2005	05/28/2005	SERGEANT AT ARMS	VN00006347-08	-$148.82
EXPENSE SUBTOTAL	**Doc Count: 6**					**-$1,758.21**
23.32.99 TELECOM CERTIFIED - OTHER						
CV050010349	05/09/2005	03/01/2005	03/31/2005	SERGEANT AT ARMS	VN00006347-07	-$186.86
CV050011815	06/09/2005	04/01/2005	04/30/2005	SERGEANT AT ARMS	VN00006347-07	-$259.35
EXPENSE SUBTOTAL	**Doc Count: 2**					**-$446.21**
23.52.01 MAILING CERTIFIED - FRANKED MAIL COSTS						
CV050008556	04/12/2005	03/01/2005	03/31/2005	DISBURSING OFFICER USPS	VN00000018-02	-$58.94
CV050009792	05/09/2005	04/01/2005	04/30/2005	DISBURSING OFFICER USPS	VN00000018-02	-$31.09
CV050011102	06/09/2005	05/01/2005	05/31/2005	DISBURSING OFFICER USPS	VN00000018-02	-$8.16
EXPENSE SUBTOTAL	**Doc Count: 3**					**-$98.19**
23.52.03 MAILING CERTIFIED - POSTAGE & OTHR-USPS						
CV050008373	04/12/2005	03/01/2005	03/31/2005	POSTMASTER US SENATE	VN00000011-01	-$2.25
CV050009676	05/09/2005	04/01/2005	04/30/2005	POSTMASTER US SENATE	VN00000011-01	-$0.80
EXPENSE SUBTOTAL	**Doc Count: 2**					**-$3.05**
25.24.01 RECORDING STUDIO CERTIFICATIONS						
CV050009012	04/12/2005	03/01/2005	03/31/2005	SERGEANT AT ARMS	VN00006347-02	-$50.00
CV050010119	05/09/2005	04/01/2005	04/30/2005	SERGEANT AT ARMS	VN00006347-02	-$100.00
CV050011417	06/09/2005	05/01/2005	05/31/2005	SERGEANT AT ARMS	VN00006347-	-$50.00

					02	
EXPENSE SUBTOTAL	**Doc Count: 3**					**-$200.00**
25.25.01 PHOTOGRAPHIC STUDIO CERTIFICATIONS						
CV050009204	04/12/2005	03/01/2005	03/31/2005	SERGEANT AT ARMS	VN00006347-03	-$10.00
CV050010458	05/09/2005	04/01/2005	04/30/2005	SERGEANT AT ARMS	VN00006347-03	-$10.00
CV050011539	06/09/2005	05/01/2005	05/31/2005	SERGEANT AT ARMS	VN00006347-03	-$10.00
EXPENSE SUBTOTAL	**Doc Count: 3**					**-$30.00**
26.12.01 O&S - STATIONERY CERTIFICATIONS						
CV050009392	04/20/2005	03/01/2005	03/31/2005	KEEPER OF STATIONERY	VN00000008-01	-$2,136.19
CV050010920	05/12/2005	04/01/2005	04/30/2005	KEEPER OF STATIONERY	VN00000008-01	-$1,244.17
CV050012167	06/15/2005	05/01/2005	05/31/2005	KEEPER OF STATIONERY	VN00000008-01	-$724.01
EXPENSE SUBTOTAL	**Doc Count: 3**					**-$4,104.37**
TOTAL CERTIFICATIONS	**Doc Count: 22**					**-$6,640.03**

QUESTIONS AND ANSWERS

JULY 21, 2005

Questions For the Record
Senate Agriculture, Nutrition and Forestry Committee
"Bio-Security Preparedness and Efforts to Address Agro-Terrorism Threats"
July 20, 2005
Dr. Maureen McCarthy

Questions from Chairman Chambliss

What measures is the Department taking to encourage the development of new tools and products to address threats to our food and agriculture sectors?

Response: As noted in the response to Q02683 above, an integrated strategy for defending against foreign animal diseases has been developed by DHS and USDA and submitted to Congress. This strategy emphasizes the development of veterinary countermeasures such as diagnostics, vaccines, and therapeutics for rapid detection and characterization of potential outbreaks.

Highlights of these efforts during FY 2004-2005 include the design and development of a high-throughput diagnostics platform for FMD and look-alike diseases to enhance surge capacity (see the response to Q02686 above), characterization and enhancement of the onset of immunity for the current generation of FMD vaccines, and selection of promising candidates for next-generation FMD vaccines and therapeutics for further development with private sector partners. During FY 2006, the new diagnostics platform will be demonstrated with partner NAHLN laboratories, and candidates for next-generation vaccines will be selected for additional FMD serotypes.

In addition, the National Center for Foreign Animal and Zoonotic Diseases, led by Texas A&M University and collaborators, is addressing potential threats to animal agriculture, including FMD, Rift Valley Fever, avian influenza, and brucellosis. The work on FMD is carried out in collaboration with the PIADC.

With respect to food security, the S&T Directorate participated in an interagency process to assess the vulnerabilities in the agriculture and food sectors (which also included the USDA and HHS), and is conducting an end-to-end systems study to define potential architectures, trade-offs, and RDT&E requirements for the protection of critical food production nodes ("food shields"). In coordination with the Food and Drug Administration's Center for Food Safety and Applied Nutrition, as well as input from the private sector, the S&T Directorate has an open program solicitation for the design and implementation of a "food sensor" to detect priority pathogens at such nodes in the dairy industry.

Finally, the National Center for Food Protection and Defense, led by the University of Minnesota and collaborators, is working to establish best practices, and to attract new researchers to manage and respond to food contamination events, both intentional and naturally occurring.

Questions from Senator Chambliss

Have issues or situations related to USDA oversight of biotech field trials (both for food and feed and non-food use) occurred where test plots or agriculture facilities have been or could be compromised or might be at risk from domestic terrorist threats (including vandalism that might disrupt the food supply) that have compromised efforts to complete research activities or safety evaluations and oversight for products intended for commercial production?

In one case in which the location of a storage facility containing a pharmaceutical crop was disclosed, the group Greenpeace is known to have visited the site and exploited the situation for its own purposes. USDA considers field trials and other locations where such crops are stored as confidential business information and therefore this information is protected from release to the public. If the information were not protected, it may be possible to imagine a situation where the safety of the food supply is threatened.

What is the cause for the extended timeframe for a mandatory National Animal Identification System (NAIS) and is there any effort at USDA to pursue a timelier implementation given our vulnerabilities to agroterrorism and intentional or unintentional disease introduction?

The participation requirements of NAIS are intended to provide results necessary to maintain the health of the national herd. USDA also wants the program to be practical for producers and others involved. Therefore, full implementation of NAIS has been planned using a phased-in approach. Stakeholder input and participation is vital during each stage in order to establish a fully functional and practical NAIS. USDA is following the standard rulemaking process while moving NAIS from voluntary to mandatory participation. The public has the opportunity to comment on any proposed regulations. NAIS is a massive undertaking and a major program that is requiring significant changes to procedure and policy; therefore, rulemaking in this case, while a lengthy process, is indispensable. The lengthy rulemaking process has contributed to the extended timeframe for a mandatory NAIS.

Animal and premises registration are projected to be mandatory by 2008, and reporting defined animal movements is projected to be mandatory by 2009. To maintain this timeline, we must: (1) publish a proposed rule establishing new requirements for premises registration and animal identification that follow NAIS standards by July 2006; (2) publish a final rule establishing mandatory animal identification and premises registration requirements by 2007; and (3) publish a final rule requiring the implementation of premises registration and animal identification as defined under NAIS program standards by January 2008.

Again, we'd like to emphasize that since the announcement of the formation of NAIS in May 2004, the system has advanced to the point where it is now capable of supporting the registration of premises and animal identification. The cattle industry has been the priority and cattle producers will be able to identify their animals in NAIS this fall.

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Questions from Senator Tom Harkin

The State Homeland Security Assessment and Strategy Program includes only a voluntary agriculture assessment. Until recently, states were prohibited from using funding from the State Homeland Security Grant Program for agrosrsid2759352 -terrorism.

- How is agro-terrorism being accounted for in the DHS reorganization being undertaken by Secretary Chertoff?

Response: A major emphasis of Secretary Chertoff's second stage re-organization (2SR) is on preparedness. The proposed Preparedness Directorate will include several of the DHS organizational elements with responsibility for agriculture and food issues, including infrastructure protection, State and local coordination, and the new Chief Medical Officer (concerning potential impacts of agro-terrorism on human health). Research, development, testing and evaluation (RDT&E) functions will remain in the S&T Directorate. In addition, the Secretary proposed a new Under Secretary for Policy, which is expected to enhance overall departmental coordination of policy and decision making, especially for cross-cutting issues like agriculture and food.

- What is DHS doing to ensure that agro-terrorism is a more robust part of the State Homeland Security Assessment and Strategy Program?

Response: Based upon the issuance of Homeland Security Presidential Directive 8: *National Preparedness* (HSPD-8), DHS has issued guidance to States to update their State Homeland Security Strategies, and will be conducting a limited pilot capability assessment in select States. In support of this updated guidance and pilot, DHS has engaged agricultural and food security subject mater experts and related agencies/offices to ensure that agro-terrorism related issues are effectively addressed in the strategy updates and assessments. In consultation with these experts, DHS will also ensure that resulting homeland security grant program guidance allows State and local agencies to use available funding resources in support of agro-terrorism related programs/initiatives, training, equipment, and exercises in support of their efforts to reduce identified vulnerabilities, meet target capabilities, and protect related critical infrastructure systems.

HSPD-8 called for an all-hazards National Preparedness Goal that established measurable priorities, targets, and a common approach to developing needed capabilities. In response to HSPD-8, the Department of Homeland Security (DHS) issued the Interim National Preparedness Goal (the Goal) and accompanying National Preparedness Guidance (NPG). The Goal established a vision for a National Preparedness System, and the NPG provided an introduction to several of the key building blocks for that system, including the National Planning Scenarios, Universal Task List (UTL), Target Capabilities List (TCL), and seven National Priorities.

As a result of these efforts, States received guidance for placing their preparedness efforts within the context of this new doctrine by updating their existing Homeland Security Strategies to ensure that they support the Goal, address the four homeland security mission areas (*prevent, protect, respond, and recover*), and reflect the seven National Priorities.

security efforts and provide a strategic plan for the use of related Federal (i.e. Homeland Security Grant Program (HSGP)), State, local, and private resources within the State and/or Urban Area before, during, and after threatened or actual domestic terrorist attacks, major disasters, and other emergencies;

On July 22, 2005, DHS published *Guidance on Aligning Strategies with the National Preparedness Goal* which details requirements for the mandatory modification of the strategies for 2006. The guidance reinforces the need to implement the National Response Plan, which includes Emergency Support Function #11; the Agriculture and Natural Resources Annex. This annex is intended to provide the structure for coordinating Federal interagency support and describes the roles and responsibilities of Federal departments and agencies when responding to an act of agro-terrorism. In states with significant agricultural assets, ODP has also been working with the states to identify and strengthen their strategies to address and protect these assets.

In addition to aligning the strategies with the Goal, the mission areas, and the National Priorities, the strategies must also address citizen preparedness and local government concerns, and identify any additional target capabilities from the Target Capabilities List (TCL) that are a priority for them beyond the National Priorities. 88 The TCL were designed to assist jurisdictions and agencies in understanding and defining their respective roles in a major event, the capabilities required to perform a specified set of tasks, and where to obtain additional resources if needed. The TCL contains capability summaries for the 36 target capabilities, including three that specifically address agricultural related issues: 1) Food and Agriculture Safety and Defense; 2) Animal Health Emergency Support; and 3) Public Health Epidemiological Investigation and Laboratory Testing.

Throughout the development and update of the State Homeland Security Strategy and Assessment processes, as well as the formation of resulting FY 2005 and the upcoming FY 2006 grant program guidance, DHS has continually solicited input from variety of agricultural and food security subject matter experts, including coordination with and input from:

- DHS/IAIP
- DHS/S&T
- DHS/FEMA
- U.S. Department of Agriculture (USDA), Homeland Security Office
- USDA, Animal and Plant Health Inspection Service (APHIS)
- USDA, Food Safety and Inspection Service (FSIS)
- Department of Health and Human Service (DHHS), Food and Drug Administration (FDA), Food Safety Staff

Through the refinement of the FY06 homeland security assessment and strategy efforts, DHS has and will continue to rely on the expertise and input from the previously identified agricultural/food security related agencies/offices to ensure agro-terrorism related issues are addressed in the development and required through the implementation of updated assessment

These existing Homeland Security Strategies were originally developed in 2003; the DHS Office for Domestic Preparedness (ODP) required that states participate in the State Homeland Security Assessment and Strategy Process, which included an optional agricultural assessment module. The risk and needs assessment generated data that was used to prepare State and Urban Area Homeland Security Strategies, submitted to ODP in 2004. The purpose of Homeland Security Strategies is to: provide a blueprint for comprehensive, enterprise-wide planning for homeland

and strategy guidance, and that these identified concerns may be addressed through available funding resources in resulting grant guidance.

States have had to fill the void left by the Federal Government. Eleven states formed the Multi-State Partnership for Security in Agriculture ("Partnership") to collaborate on surveillance of, preparation for, and response to threats in agriculture, whether intentionally introduced or naturally occurring, and coordinate these efforts with all levels of government. This is an Iowa-led initiative, and Secretary Ridge understood the importance of this effort, granting the Partnership $2 million in seed money to continue its work.

- Is there a commitment at DHS to continue funding the Partnership?

Response: The Multi-State Partnership for Security in Agriculture has collaborated to develop a suite of best practices, model templates, and collaboration tools in support of nation-wide surveillance, preparedness, and response activities for possible agricultural and food security threats or attacks.

DHS is committed to support the continuation of the Partnership program through further developing and distributing the best practices, model templates, and collaboration tools that have been developed to states nation-wide, as they may use these resources to further support their agro-terrorism related efforts. Additionally, DHS will encourage Partnership states, as well as all other states across the nation, to utilize these tools and leverage existing SHSGP funds to implement any necessary agro-terrorism related prevention, protection, response, and recovery capabilities.

- If funding is forthcoming, how will the Partnership be funded by DHS?

Response: While the Department does not plan to provide specific funding for this project, each State in the partnership has the ability to use funds provided by the Department's Office for Domestic Preparedness to support approved agro-terrorism related projects such as the Partnership. As with other uses of funds, projects must be consistent with each State's homeland security strategy and must fall within the applicable allowable costs guidelines of the program.

There have been many reports indicating that the number of agricultural inspections at our borders has significantly decreased as the number of imports have increased.

- What are the reasons for this decline in inspections?

Response: The Secretaries of Agriculture and Homeland Security are working together to identify the reasons for declining agricultural inspections and to identify potential areas for improvement.

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USDA and DHS have entered into a Joint Agency Quality Assurance Plan (JAQAP) and have agreed to conduct joint quality assurance reviews of ports of entry (POE). This joint program is intended to study the performance of the agricultural mission under DHS and identify the best business practices of individual ports. If the JAQAP does a port review and finds a decline in inspections, the reasons for a port's declining inspections will be explored and actions to improve the port's performance will be recommended. This program is part of the overall agreement between the two agencies. The vision statement of the Joint Quality Assurance Plan reads as follows:

JAQAP will provide suggestions for preventing terrorists and terrorist weapons in the form of agroterrorism from entering the United States. JAQAP will assist Customs and Border Protection to safeguard agricultural and natural resources from the intentional (agroterrorism) or unintentional introductions of animal and plant pests and disease into the United States.

In FY 2005, the Joint Team will have conducted four port reviews. Six more port reviews are expected to take place during the next calendar year. These cooperative efforts will identify weaknesses in the port's agricultural operations and suggest areas and ways to address those areas of concern. The Joint Teams' first review was in Philadelphia in December 2004. The second and third reviews took place in Miami and Long Beach, California. While all of the reviews noted a change in the rate of interceptions, the Joint Teams found that all of the ports had initiated a variety of methods to address agricultural concerns, inspections, and operations. CBP has been actively recruiting and hiring new Agricultural Specialists and very successful in filing new officers training courses. The Joint Team has offered CBP an opportunity to study "best practices" and share them within CBP. Additionally, CBP conducted extensive training to make this agency into an effective and efficient operation protecting the United States. These efforts involved agricultural training as well as other cross training to increase the number of officers and specialists at the borders aware and knowledgeable about the agricultural issues.

The Department also plans to increase hiring of Agriculture Specialists and Agriculture Supervisors. In November 2004, DHS advertised 129 government-wide agricultural specialist positions. In addition, DHS approved twenty training classes for new officers. Classes began in the summer of 2004, with fourteen beginning in FY05 for the training of 504 new Agricultural Specialists, and six commencing in FY06 for the training of 216 new specialists. Based on the scheduling of classes this means that 720 new Agricultural Specialists are expected to pass the New Officer Training (NOT) and begin working at Ports of Entry by February 2006.

In addition to new officers, DHS has identified the need to replace and increase the number of Agricultural Supervisors. The Department began issuing vacancy announcements for new Agricultural Supervisors during the week of February 7, 2005. The added Supervisors will enhance the DHS agricultural inspection infrastructure as the number of Specialists and their workloads increase.

The Department also plans to improve agricultural targeting to make more interceptions of pests and diseases. The assignment of Agricultural Specialists to the Advance Targeting Units (ATU)

will greatly enhance the ability of DHS to more effectively target passengers and commodities at all the POEs. "Smarter" targeting will increase the number of interceptions by focusing on the people and commodities of greater risk. A number of Agricultural Specialists have already received the ATS targeting training necessary to be part of an ATU team.

DHS has developed and delivered ATS training aimed solely at Agricultural Specialists. Three classes were completed by August 2005. It is planned to have ATS training for Agricultural Specialists in air cargo and land border POEs completed by the end of FY 2006.

As DHS targets higher risk commodities, it is not necessary to keep pace with the number of inspections of low risk or random targets. Comparing the number of interceptions for the first three quarters of FY 2004 versus the same period in FY 2005, maritime cargo interceptions have risen twenty six percent.

- How has DHS improved its communications with USDA to correct this and other coordination problems at the border?

Response: DHS executed a Memorandum of Agreement (MOA) between it and USDA at the time of the merger. In general this MOA spelled out the agricultural inspection functions that were transferred to CBP. It was anticipated that further details would be worked out in appendices to the MOA Articles. The two agencies have now executed appendices to all of the articles except Article 4 concerning training (which is very close to an agreement). Training between the two agencies has worked exceedingly well. The holdup in completing the appendix is a minor problem in that staffing turnover has impeded the negotiations. CBP has made great efforts to place Agricultural Specialists in all its field offices and this has greatly increased the ease of communication between the two agencies. Additionally, different CBP Field Directors have hosted round-table discussions between state, local and federal stakeholders. These meetings have been done in conjunction with USDA. The Commissioner of CBP and the Administrator of USDA APHIS now meet on a quarterly basis and high ranked staff members meet on a weekly basis.

CBP has increased the number of jointly sponsored special operations. CBP has also directed that all ports institute Pest Risk Committees that involved USDA and state officials on a frequent and reoccurring basis.

In summary, CBP and USDA have taken proactive steps to improve communication at all levels of the organization.

What steps has DHS taken to correct security problems at the Plum Island Animal Disease Center?

Response: Details are provided in the report entitled "Plum Island Animal Disease Center: Corrective Action Plan to Address Needed Facility and Systems Upgrades", which was submitted to Congress as requested.

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The Report describes numerous steps that DHS has taken to increase security at PIADC, including: installation of new access security systems, intrusion detection systems, alarms, and closed-circuit TV (CCTV) surveillance for critical areas of the bio-safety level 3 (BSL-3) laboratory facilities; the increased security force as well as the number of patrols; established strict entry and exit rules to control access to the bio-containment area; and established policy and procedures for use of force and weapons. The report also includes additional steps PIADC is now planning, including the installation of a new access security system for audit tracking of personnel access to freezers used for animal pathogens and select agents, as well as further increases to the physical security around the bio-containment compound.

Questions Submitted by Senator Harkin

Please describe the steps being taken to implement the National Animal Identification System. When will it be completed and is it being expedited by USDA as previously promised?

We would like to first stress that the National Animal Identification System (NAIS) is not a program to be "completed;" rather, it will be ongoing since new animals will be added to the system continuously and the collection of their movements will be necessary.

As far as the deployment of the NAIS components, premises identification (ID) is already in place. In fact, 49 States, 2 U.S. territories, and 5 Native-American Tribes are currently operational on premises registration. Wyoming is still working on becoming operational using Nebraska's NAIS-compliant system with an anticipated deployment by the end of August 2005. There are over 103,000 premises registered across the United States.

In addition to premises ID, animal ID will be operational this fall on a voluntary basis through the Animal Identification Number (AIN) system. Our goal is to be operational with the AIN system and roll out the "840" number in September 2005. We have made considerable progress to reach that goal. The AIN Management System, which allocates the AIN to approved identification technology companies and records the distribution of devices to premises, has been developed and thoroughly tested. In November of 2004, an interim rule published by USDA established the "840" number as an official identification number for NAIS. The "840" number is a unique, 15-digit identification number that can be used for all regulatory programs as well as programs managed by the industry.

The NAIS Strategic Plan outlines the phased-in implementation steps for NAIS requirements for premises and animal identification to be mandatory. Reporting animal movements would be required by January 2009. However, it is important to note that a large portion of the systems to support premises registration and animal identification are in place now and ready to be utilized on a voluntary basis. The development of such information systems demonstrates the high priority that USDA has given to advance NAIS in a timely manner. The regulation being considered to move to mandatory participation requirements will be a significant rule and will require adequate time for public comment and review of these comments by the Administration. We feel market forces will continue to encourage, if not require, participation in the near future. Therefore, our priority has been to have the underlying components of the system operational as quickly as possible.

USDA's area and regional emergency coordinators provide states with a point of contact to help with preparing for an agricultural emergency. What specific efforts are being made at USDA to better communicate with the states, particularly within the area of regional coordinators? Have all of the coordinator positions been filled? Will more positions be created in order to more accurately fulfill the coordinators' advisory role to states?

As you note, USDA's Area Emergency Coordinator program enhances communication with States and facilitate local, State, regional, and national coordination efforts during emergency situations. The goal of the program is to place 43 Area Emergency Coordinators across the country, 1 for each of APHIS' Area-Veterinarian-in-Charge offices. The coordinators would be the point of contact for each State on animal health emergency management issues. Communication would be facilitated by joint participation in coordination meetings, test exercises, guideline production and review, training opportunities, and Department of Homeland Security programs and projects related to agriculture and coordination of Emergency Response Function #11.

Given available funding levels, APHIS has filled 16 of the 43 positions. Should additional resources become available, APHIS intends to fully implement the program.

Please describe any efforts undertaken by USDA to create and/or test more effective and responsive methods for identifying a widespread infectious animal or

plant disease outbreak. How much funding has been devoted to these efforts? If no efforts have been undertaken, why not?

One of USDA's key goals is to expand surveillance and monitoring systems to provide early detection and tracing of diseases and outbreaks. Quite simply, if pests and disease incursions can be found in their early stages, control and eradication measures will be more effective and less costly. To this end, USDA's fiscal year 2006 budget request to Congress included an increase for the Comprehensive Surveillance System to better protect the Nation's animals from the threat of domestic, emerging, and foreign animal diseases. The surveillance system includes cooperative efforts to conduct surveillance and diagnostic programs for significant livestock diseases, as well as enhance animal health monitoring activities across the country.

The FY 06 budget also provided an overall $17 million increase for the plant pest detection line item. Funding for this program supports surveys for high-risk plant pests, as well as the hiring of additional APHIS pest survey specialists. The specialists work with State cooperators and plant pest identifiers to enhance efforts to identify pests detected as part of the survey programs mentioned above.

Robust pest and disease survey efforts require the support of strong diagnostic programs. For animal health, USDA's National Centers for Animal Health, which includes APHIS' National Veterinary Services Laboratories (NVSL) and the Center for Veterinary Biologics, has received $401,900,000 in appropriated funding from Congress for construction of modern laboratory and animal facilities in Ames, Iowa. The remaining $58,800,000 for the modernization project is included in the fiscal year (FY) 2006 Agriculture Appropriations bill under consideration by Congress. Once completed, the modernized facilities in Ames will better enable USDA and its National Animal Health Laboratory Network (NAHLN) partners to prevent, detect, and respond to the purposeful or accidental introduction of a foreign animal disease in the United States.

In regard to safeguarding systems in place to guard against and respond to significant plant pests, APHIS works with other USDA agencies to develop effective survey, computer modeling, diagnostic, data management, laboratory certification, and secure communications systems. These systems are required to support the protection, preparedness, response, and recovery functions of the National Response Plan's Emergency Support Function (ESF) #11. In support of the ESF #11, APHIS has many ongoing initiatives, such as research performed in Federal and State laboratories to characterize plant pathogen genomics and disease epidemiology. These types of initiatives provide the foundation for early detection and identification of plant diseases.

What steps is USDA taking to build U.S. supplies of ready-to-use vaccines?

APHIS administers a National Veterinary Stockpile (NVS) for specific, high threat foreign animal diseases. NVS is capable of maintaining vaccine for use in the United States in the event of a significant foreign animal disease outbreak. APHIS will use the NVS to consider and obtain "ready-to-use" vaccine product. The goal is for NVS to

become one component of an overall response planning and recovery effort to provide the best possible protection against an attack on our agriculture and food system.

An NVS Steering Committee, which includes representatives from DHS and the Department of Health and Human Services, has been established as a recommending body to determine what is contained in the NVS. The NVS Steering Committee's charter charges the Committee to ensure that decisions regarding the composition, inventory, storage, deployment, use, and staffing of the NVS are based on the most current threat assessment, the most rigorous science available, the best predictive modeling possible, and the best expert advice.

The fiscal year 2006 budget proposes $8.12 million for APHIS to continue stockpiling FMD vaccines and supply NVS. APHIS has approved a position for a National Veterinary Stockpile Manager and efforts are underway to reduce delays in obtaining "ready-to-use" vaccine.

Is there a way to store the two components of FMD here in the U.S. so that we don't have to ship the vaccine overseas to be activated?

As you know, there are many facets to this issue. The main consideration is that the vaccine needs to be in concentrate form for long-term storage. If it is stored in ready to use form, the shelf life of the product is only 18-24 months. While there is some discussion in the scientific community that finished vaccine could be stored in liquid nitrogen over time, more study is needed before USDA could consider such an option.

Another significant consideration is that the vaccine cannot be produced in the United States because the process requires the growth of large amount of foot and mouth disease virus. The 2 components of the vaccine (vaccine concentrate and adjuvant) can be stored in the United States, but no commercial vaccine manufacturer in the country will combine the 2 products and guarantee the efficacy of the final vaccine. The vaccine, therefore, can only be finished by the manufacturer overseas.

And finally, there are several strains of the foot and mouth disease virus. It is impractical (and exceedingly expensive) to maintain stockpiles for every one. By storing vaccine concentrate and adjuvant in the United States and then shipping these components overseas, the manufacturer can produce finished vaccine to address the strain responsible for the outbreak in the United States.

In light of these issues, there is exploration ongoing regarding the development in the United States of an alternative vaccine that might address the concerns outlined above. It is estimated, however, that this process is still 3 to 5 years away from completion.

In the meantime, USDA also continues to evaluate related concerns, such as the security and costs associated with the storage of ready to use foot and mouth disease vaccine in the United States. Additionally, should there be a detection of the disease in the United States, USDA would order the immediate production of finished vaccine at the

manufacturer's facility overseas. Therefore, if a decision is made to vaccinate animals against the disease, vaccine production and shipment to the United States would already be underway.

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Questions from Senator Cochran

Could you please comment on the current capabilities and status of the Department of Homeland Security's Plum Island, New York, Animal Disease Facility?

Response: See response to Q02694 above.

On June 1, 2003, pursuant to Section 310(a) of the Homeland Security Act of 2002, Public Law 107-296, whereby the Secretary of Agriculture transferred PIADC to the Secretary of Homeland Security, including the assets and liabilities of PIADC, DHS assumed responsibility for the PIADC operations, including facilities and grounds, security, fire protection, emergency medical services, environmental management, and maintenance.

PIADC is a unique scientific research facility and a critical national asset. PIADC provides the only U.S. research and confirmatory diagnostic capability for specific high-consequence foreign animal diseases, and is the only laboratory in the United States equipped with research facilities and livestock animal rooms that permit study of these diseases in livestock, such as cattle, sheep, and swine. It is the only U.S. laboratory authorized by the Secretary of Agriculture under the provisions of 21 USC §113(a) to study foot-and-mouth disease. PIADC is vital to successfully implementing a national strategy for protecting U.S. agriculture from a bioterrorist attack involving the intentional introduction of foreign animal diseases such as foot-and-mouth disease (FMD).

PIADC supports the research mission of DHS, the United States Department of Agriculture's (USDA) Agricultural Research Service (ARS), and the USDA's Animal and Plant Health Inspection Service (APHIS). PIADC supports the goals of agricultural bio-security by developing threat and vulnerability data to anticipate bioterrorist attacks against agriculture, and by strengthening our capability to assume an effective response to, and recovery from, an attack by developing medical countermeasures such as vaccines, treatments, and diagnostics. ARS scientists are able to fulfill USDA research goals involving high-consequence foreign animal diseases (FADs) using the unique bio-safety level 3 (BSL-3) agricultural containment facility at PIADC. ARS performs both basic and applied research involving FADs to obtain new knowledge of the route of infection of pathogens, method of colonization, target organs, and immunopathology to create new strategies to prevent and control livestock diseases. PIADC houses the APHIS Foreign Animal Disease Diagnostic Laboratory (FADDL), which is the only confirmatory diagnostic laboratory in the country for high-consequence FADs. In Plum Island facilities, APHIS provides diagnostic evaluation of samples collected from U.S. livestock or from imported animal products to rule out introduction of FADs, develops diagnostic tests for

FADs, and trains veterinarians in recognition and diagnosis of FADs through regular courses taught at PIADC.

DHS S&T takes pride in the efforts of its staff including PIADC personnel for the great strides made during the Department's first year as the responsible agency for PIADC. DHS has developed and begun to implement a comprehensive corrective action plan to maintain an aging but critical National asset in a relatively short period of time. DHS S&T is committed to investing in key infrastructure upgrades to maintain this critical national asset to ensure it can perform its vital mission.

DHS realizes however that PIADC is now 50 years old and is becoming increasingly more costly to maintain, and the laboratory and test space in the current facility is insufficient to support the increased levels of research and development needed to meet the growing concerns about accidental or intentional introduction of foreign animal diseases into this country, and it is completely inadequate to address zoonotic diseases.

Recognizing the needs described above, the President requested $23M in FY06 for the design and initiation of a National Bio and Agrodefense Facility (NBAF). In preparation for this, DHS has undertaken during FY 2005 a conceptual design study to better characterize the key programmatic requirements driving the NBAF design and to explore the cost benefit tradeoffs associated with each of these drivers.

In light of the President's Fiscal Year 2006 Budget Request for the creation of the National Bio and Agro-defense Facility as part of the Department of Homeland Security, what type of commitment from the Administration and the Department do you see in sustaining the research capability of the federal government to anticipate, prevent, respond to, and recover from the introduction of biological threats such as foreign animal diseases?

Response: As summarized in the response to Q02685 above, the S&T Directorate is funding in FY 2005 a conceptual design study to determine the programmatic requirements for the National Bio and Agrodefense Facility (NBAF). The proposed FY 2006 budget for the S&T Directorate includes a request for $23 million for the architectural and engineering design, and pre-construction costs, for the facility. In partnership with USDA, DHS remains committed to fulfilling its obligations accompanying the transfer of the PIADC to DHS in 2003.

Questions Submitted by Senator Grassley

Can you provide a summary of the material and resources that USDA has at its disposal if an outbreak of a disease such as foot and mouth disease were to occur at this moment?

APHIS administers a National Veterinary Stockpile (NVS) for specific, high threat foreign animal diseases. NVS is capable of maintaining vaccine for use in the United States in the event of a significant foreign animal disease outbreak. APHIS will use the NVS to consider and obtain "ready-to-use" vaccine product. The goal is for NVS to become one component of an overall response planning and recovery effort to provide the best possible protection against an attack on our agriculture and food system.

The fiscal year 2006 budget proposes $8.12 million for APHIS to continue stockpiling FMD vaccines and supply NVS. APHIS has approved a position for a National

Veterinary Stockpile Manager and efforts are underway to reduce delays in obtaining "ready-to-use" vaccine.

APHIS maintains a national network of personnel to monitor for and, if necessary, respond to outbreaks of significant foreign animal diseases (FAD). This network includes:

- An Area Veterinarian in Charge (AVIC) assigned to all States to administer surveillance and preparedness operations along with State veterinary officers.
- Area Emergency Coordinator (AEC) positions strategically placed throughout the United States so as to cover all States; help support and improve Federal, State, and Tribal preparedness and response to FAD emergencies.
- A cadre of more than 40,000 accredited private veterinary practitioners who report any suspected FADs to Federal or State officials.
- A total of 450 specially trained foreign animal disease diagnosticians from State, Federal, and military ranks as well as a cadre of poultry industry veterinarians who are highly trained in diagnosing FADs.

These efforts are also supported by world-class diagnostic capabilities through APHIS' National Veterinary Services Laboratories (NVSL). NVSL, in turn, is also supported by the National Animal Health Laboratory Network, which provides additional FAD diagnostic capabilities at USDA approved State animal health diagnostic labs.

APHIS already maintains the FAD management infrastructure required to conduct an emergency response program. The response would occur at the local level in accordance with the National Animal Health Emergency Management System's (NAHEMS) guidelines for highly contagious diseases. The NAHEMS guidelines provide an operational framework for APHIS to respond to animal health emergencies.

If the scope of a FAD outbreak is beyond the immediate resource capabilities of APHIS and the affected State's animal health officials, additional resources can be obtained through the following mechanisms:

- Under the National Response Plan's (NRP) Emergency Support Function #11, APHIS can implement an integrated Federal, State, Tribal, and local response to a FAD or zoonotic disease outbreak. This mechanism ensures animal health emergencies are supported in coordination with the emergency support function that covers public health and medical services.
- APHIS can request additional animal health personnel through the National Animal Health Emergency Response Corps (NAHERC). The NAHERC is composed of private veterinarians and animal health technicians available on short notice.
- APHIS can also request resources through the International Animal Health Emergency Reserve (IAHER), an international agreement for resource sharing with six signatory countries: Australia, Canada, New Zealand, Great Britain, and Ireland, in addition to the USA.

Upon detection of an FAD outbreak in livestock or poultry, APHIS would quickly establish a national communications and coordination plan which includes—in the case of a zoonotic disease—the notification of the U.S. Centers for Disease Control and Prevention to initiate their involvement, in coordination with State and local health departments, in an effort to minimize disease transmission from animals to humans. If necessary, APHIS would declare the situation an Incident of National Significance evoking the full support and coordination of the NRP.

Would the supplies and tools currently on hand be sufficient to address a worst case scenario such as the FMD outbreak in the United Kingdom a few years ago or the avian influenza outbreak we've seen in Asia?

Given the existing resources outlined above, as well as the additional support and resources available to USDA through the NRP, we believe that we would be able to address an outbreak of a significant FAD in the United States.

Is USDA adequately prepared for the outbreak of diseases such as FMD or AI or other infectious animal diseases should they occur in multiple sites simultaneously?

We fully recognize that multiple FAD outbreaks in the United States would stress the existing systems for managing such situations. Again, however, given the resources outlined above, the high level of planning and coordination already underway by the Federal Government and its State and local partners, and the additional support and resources available through the NRP, USDA and its myriad cooperators would make every effort to successfully respond to multiple FAD outbreaks in the United States.

What assimilation or "dress rehearsal" exercises has USDA done since 9/11 to determine what is needed to address disease outbreaks?

As APHIS and its partners continue to refine their emergency response infrastructure and capabilities, the Agency and its cooperators routinely assesses the lessons learned not only from FAD exercises, but also "real world" incidents. Since 2001, these incidents have included the BSE investigations in Texas and Washington; outbreaks of avian influenza in Canada, Virginia, and Texas; the detections of monkeypox in the United States; and the outbreak of exotic Newcastle disease in California and other southwestern States. All of these situations have involved emergency response activities carried out by multiple Federal, State, and local personnel, and each has provided a unique set of challenges to responders.

The foreign animal disease response exercises that USDA has participated in since 2001 include the Tripartite series (the *Amistad, MayDay*, and *Equinox* exercises), as well as exercises co-hosted with other agencies. These include *Operation Aphtosa* and the *Crimson Sky* exercise. The data and results collected as part of these exercises is being used to develop a comprehensive exercise program that will better test participating agencies' decisionmaking and response capabilities. In addition, the exercise program

will help to identify both the "quick to change" items that can be remedied by modifications to existing guidelines, as well as the "longer term" lessons that may require additional research or policy discussions by USDA.

Questions Submitted by Senator McConnell

As you know, in the last month an animal infected with BSE was discovered in the United States. Authorities worked around the clock to quickly determine the cow's origin, its age, offspring and cohorts. In the end, USDA conducted DNA confirmatory testing because it is the only absolute method to confirm identity of a particular animal. As the technology has improved and advanced to the point that individual animals can be rapidly identified, do you believe that DNA analysis has a role to play in the larger animal ID system? Do you believe the benefits of DNA analysis would justify the additional costs to the federal government and producers?

DNA analysis has had a role in APHIS trace-backs of the 2 BSE cases found in the United States. DNA is currently used by many industry groups including breed associations. The technology is currently mature and its associated costs are coming down. However, the administration of extending DNA testing to every individual livestock animal in the United States would be a large, costly task.

The current total cost estimate for the National Animal Identification System (NAIS) through fiscal year (FY) 2009 is over $750,000,000. While DNA is a valuable technology that can be used to validate an animal's identification, the cost of collecting DNA on the entire U.S. livestock population cannot be justified at this time. However, technology that validates animal ID and provides a measure of accuracy could be considered for a smaller percentage of the animal population, in particular high risk animals and/or animals of special interest. USDA continues to evaluate such technologies and believes there is a place for biometric technology within NAIS, yet acknowledges that it must be both practical and affordable for the producers.

Questions For the Record
Senate Agriculture, Nutrition and Forestry Committee
"Bio-Security Preparedness and Efforts to Address Agro-Terrorism Threats"
July 20, 2005
Dr. Maureen McCarthy

Questions from Senator Pat Roberts

Last week Secretary Chertoff announced the results of his Second Stage review of the Department. As a result of this review, he announced the creation of the position of "Chief Medical Officer" within the Department. Can you tell me what role this new position will play in regard to food and agriculture security and the threat of many of these diseases on human health?

Response: The CMO is also responsible for coordination of medical issues with other Departments in the Administration and the White House. Our view of preparedness includes the preparation for consequences of catastrophic incidents, many of which are medical in nature, which is one of the principal reasons for standing up the Office of the CMO. This preparation would include full engagement with state and local authorities, associations of medical professionals, and other stakeholders who deal with medical consequences of natural disasters or terrorist attack.

Also, in the new intelligence arm of DHS, where will food security and agro-terrorism be assigned?

Response: Lead responsibility for intelligence assessments regarding agroterrorism resides with the DHS Homeland Infrastructure Threat and Risk Analysis Center (HITRAC). HITRAC coordinates assessments in this area with the former Emerging Weapons and Techniques Branch of the Department Assessments Division, IA-D, to cross-matrix and integrate intelligence information with other biological warfare-related threats.

Is there already a portion of what was formerly Information Analysis and Infrastructure Protection assigned to looking at agriculture and food as part of our critical infrastructure?

Response: The Office of Infrastructure Protection will continue to work with the agriculture and food sector through the developed structure in place to coordinate the implementation of both HSPD-7 and HSPD-9. There is a developed Food and Agriculture Sector Coordinating Council (F&ASCC) to provide a means for the government to partner with the private sector to gain broader understanding of what is critical within the sector, how it is vulnerable, how to shield what is critical and vulnerable and how to return to normalcy if an attack occurs. Further, DHS has joined with our federal, state and local sector agencies to create the Food and Agriculture Government Coordinating Council (F&AGCC) to better coordinate across all level of government in our effort to protect this critical infrastructure and to better collaborate with the private sector. HITRAC will provide the intelligence capabilities for collection and analysis of information concerning threats, delivery systems and methods that could be directed against the food and agriculture sector.

What part of the Department will now be responsible for assessing our vulnerability in this area?

Response: The Office of Infrastructure Protection, in partnership with government and private sector via the F&ASCC and the F&AGCC have established an interagency, public private effort

project with the FBI to conduct detailed vulnerability assessments across the sector. This effort is designed to enable industry and government to better understand what is critical, how it is vulnerable and how it can be shielded against acts of agro-terrorism. Further, this effort will improve the ability of law enforcement, at all levels of government, to partner with the private sector to improve our overall sector protective posture and to improve law enforcement's ability to respond to and investigate acts of agro-terrorism.

Your prepared testimony discusses the activities you will be taking in 2005 and 2006 related to the threats posed by Foot-and-Mouth Disease and how to respond and protect the critical infrastructure. How will the efforts that USDA has already conducted on this front through the Crimson Sky simulation tie into your efforts?

Response: The Crimson Sky exercise strongly influenced multiple elements of the Department of Homeland Security's (DHS) Science and Technology (S&T Directorate' s agricultural program. Two current projects specifically address two of the top "critical needs" identified in the Crimson Sky exercise: a national-scale coupled epidemiological and economic model for foot-and-mouth-disease (FMD), and development of a high-throughput diagnostics capability for FMD and look-alike diseases.

In addition, since June 2003, the S&T Directorate has worked closely with the Department of Agriculture (USDA) to develop and coordinate a national strategy for research and diagnostics for foreign animal disease, initially focused on diagnostics, vaccines, and therapeutics for foot-and-mouth disease (FMD). Details of this strategy have been provided in two reports submitted to Congress in January 2005 (to the U.S. House of Representatives Committee on Appropriations, Subcommittee on Homeland Security).

During FY 2006, the S&T Directorate is planning a crisis action planning exercise for DHS management on a FMD scenario, as other FMD scenarios to date (e.g., Crimson Sky) were conducted before DHS was stood up in March 2003. This exercise will be followed during FY 2006 with an inter-agency FMD exercise, which will include participation by USDA.

Your testimony discusses efforts to expand the development of current and new veterinary countermeasures. How do you prioritize these research areas? Also, what if anything, are you doing on the plant side?

Response: As in response to Q02683 above, the overall strategy for addressing veterinary countermeasures has been documented in the joint DHS and USDA national strategy for research and diagnostics for foreign animal diseases. Further prioritization of specific threats are based on recommendations from several inter-agency sources, including the Office of Science and Technology Policy(OSTP)/Rand Blue Ribbon Panel, the agricultural working group of the WMD Medical Countermeasures Working Group, and most recently the National Science and Technology Council (NSTC) Subcommittee on Foreign Animal Disease Threats. In the future, these priorities will also be informed by the periodic risk assessments that DHS is charged with

performing under its responsibilities in the President's "Biodefense for the 21st Century" (HSPD-10).

With respect to crop defense, the S&T Directorate is funding during FY 2005 an end-to-end systems study on the crop pathogen, soybean rust, which arrived in the U.S. during the fall of 2004. This study will be part of laying the foundation for additional efforts on potential crop bioterror agents.

Your testimony briefly touches on some of the challenges facing the Plum Island facility due to its age, size, etc. You also mentioned that you are looking at beginning conceptual designs for a next-generation facility. On this front, I assume that you would want this to be a BL-4 level facility? Are you looking at simply replacing the current structure on Plum Island, or would you consider moving it elsewhere?

Response: The 'next-generation facility' is referred to as the National Bio and Agrodefense Facility (NBAF). A conceptual design study is being undertaken during FY 2005 to better characterize the key programmatic requirements driving the NBAF design and to explore the cost benefit tradeoffs associated with each of these drivers.

This conceptual design will explore three major NBAF options of increasing capability:

1. Keep the scope the same as the current Plum Island Animal Disease Center (PIADC) mission but build the facilities required to meet the needs of the first half of the 21st century;
2. Expand the scope to include additional agriculture bio-containment laboratories at bio-safety level 3 agriculture (BSL-3 Ag), and possibly bio-safety level 4 (BSL-4) for foreign animal and zoonotic diseases; or
3. Add expanded test and evaluation facilities to support non-clinical testing under the Animal Rule needed to support advanced development of security medical countermeasures by the Department of Health and Human Services (HHS).

Experts from DHS, USDA and HHS, are reviewing the key programmatic requirements for each of these options in order to assess key facility determinants such as the amount and type of required laboratory and support space.

Options and decisions on the level of bio-containment required by the facility, as well as the location of the facility, have not been made at this time, and will be informed by the outcome of the conceptual design study.

In the event of a crisis situation created by the intentional introduction of a disease, do you have the surge capacity necessary to handle the large number of samples it could create?

Response: A critical component of the nation's infrastructure to provide surge capacity during an outbreak is the National Animal Health Laboratory Network (NAHLN) coordinated by USDA. The associated operational and policy issues concerning planning and implementation of

surge capacity in the NAHLN thus reside with USDA Animal and Plant Health Inspection Service (APHIS).

As sample processing and analysis in excess of a few hundred samples per day in these laboratories would currently be challenging, the S&T Directorate is working closely with USDA and its NAHLN partners to assess potential technological options for significantly increasing this surge capacity. During FY 2004-2006, the S&T Directorate is funding a demonstration project to develop a high-throughput multiplexed diagnostics platform for FMD and look-alike diseases, with a planned capacity of thousands of samples per day per platform. This demonstration is being carried out in close cooperation with member laboratories of the NAHLN, and represents a collaborative effort between the S&T Directorate and USDA APHIS to assess the actual requirements (instrumentation, operations, staffing, funding) for such scalable surge capacity.

Will you please provide me and the Committee with a copy, or outline of DHS' strategic plan for food and agriculture defense, including infrastructure and research plans, the person coordinating all of those plans, estimated funding needs, and estimated staffing needs and assignments over the next five years?

Response: Overall coordination for food and agriculture defense is derived from interagency interactions at multiple levels.

Overall Federal coordination for homeland security policy and research is provided by the Executive Office of the President, and its Homeland Security Council (HSC) and National Science and Technology Council (NSTC), respectively.

In particular, the HSC Program Coordinating Committee for Agriculture, Food, and Water provides interagency coordination on related policy and operational issues, including the implementation of "Protection of United States Agriculture and Food" (Homeland Security Presidential Directive/HSPD-9).

Furthermore, interagency Working Groups convened by the HSC and NSTC provide additional forums for interagency input and discussion on policy, and research issues, respectively. Most recently, for example, the Office of Science and Technology Policy (OSTP) has established a NSTC Subcommittee on Foreign Animal Disease Threats (co-chaired by DHS and USDA) to ensure coordination of federally funded research efforts to protect against agro-terrorism.

Several of the DHS organizational elements that are concerned with agriculture and food issues (e.g., the S&T and Information Analysis and Information Protection [IAIP] Directorates) are very active in these inter-agency discussions.

In addition to these formal inter-agency mechanisms, departments and agencies interact and plan strategically around priority program areas of mutual interest and responsibility. E.g., since June 2003, DHS S&T Directorate and USDA (ARS, APHIS) have collaborated on the development

and implementation of a joint research and diagnostic strategy for foreign animal disease at the PIADC, initially focused on diagnostics, vaccines, and therapeutics for foot-and-mouth disease.

As summarized in the response to Q02683 above, reports on this joint DHS and USDA strategy were provided to Congress in 2005 (to the U.S. House of Representatives Committee on Appropriations, Subcommittee on Homeland Security). We will be pleased to provide you and the Committee with copies of these reports.

A PIADC Board of Directors has been established to provide additional coordination for planning and implementation of the strategy. The Board is chaired by the Director of the S&T Directorate's Office of Research and Development, and includes the Administrators of both ARS and APHIS. The Board provides a venue for the necessary discussions and coordination for programs, funding, and staffing requirements.

Most recently, the PIADC Board of Directors has established a Joint Federal Working Group on Research and Diagnostic Development for Foreign Animal and Zoonotic Diseases to function as a program management element to facilitate the coordination and synchronization of planning, management, and scientific interaction in areas of mutual interest among Federal research agencies or institutes. The Working Group will function as a forum for alignment of mission-objectives across specific infrastructure sectors in order to enhance protection of animal health and public health by Federal agencies.

By means of the above venues, operating at multiple levels within the Federal research and development enterprise, DHS organizational elements, and their colleagues in other departments with roles and responsibilities for agricultural and food issues, provide support to the Secretary of DHS in his role of interagency coordination. The proposed DHS Office of Policy and the new DHS Chief Medical Officer are expected to provide additional conduits for enhancing this overall coordination.

Finally, the IAIP Directorate has the DHS lead for the protection of the nation's critical infrastructures, including those for the agriculture and food sectors. These efforts include the development of the National Infrastructure Protection Plan, and coordination (with USDA and HHS) of the Food and Agriculture Sector Coordinating Council, and the Government Coordinating Council.

Senate Food, Nutrition, and Agriculture Committee
Hearing on Biosecurity and Agroterrorism
USDA Questions for the Record

Questions Submitted by Senator Roberts

Your prepared testimony discussed the research you are doing to develop rapid diagnostic tests for the identification of the most dangerous animal diseases to the U.S. livestock industry. You mention several diseases you have already developed tests on. The development and distribution of rapid test kits was a proposal I had in my legislation I introduced on this topic in 2001, so I applaud your efforts in this area.

I was wondering if you could tell us how these tests are being distributed to the states? Are they located at state laboratories, universities, with law enforcement, etc.?

USDA's Agricultural Research Service (ARS) is developing, or has developed, rapid detection capacity for priority agricultural threat agents, such as foot and mouth disease, rinderpest, African swine fever, classical swine fever, contagious bovine pleuropneumonia, lumpy skin disease, vesicular stomatitis virus, highly pathogenic avian influenza, virulent Newcastle disease, wheat rust, downy mildew of corn, and several other "look-alike" diseases. ARS is cooperating with a consortium of university and private sector partners on this rapid detection capacity; however, related work on high consequence pathogens will be restricted to ARS biosafety level 3 facilities in Ames, Iowa; Plum Island, New York; Laramie, Wyoming; Athens, Georgia; and Fort Detrick, Maryland.

For its part, USDA's Animal and Plant Health Inspection Service (APHIS) validates the tests as they are developed; prepares surveillance/response plans that include the appropriate use of the tests; and then, on the animal health side of the Agency, deploys validated tests through the National Animal Health Laboratory Network (NAHLN). The surveillance plans ensure that appropriate samples are selected and tested. The response plans describe the steps to be taken in the event of an inconclusive test result.

It is important to note that only laboratories that are part of the NAHLN and have, among other things, adequate laboratory space, trained and proficiency-tested personnel, and relationships with State and Federal law enforcement offices are approved to conduct these types of rapid tests. While some of the rapid tests may become commercialized, it is not envisioned that they would be used by first responders. Rather, they will be utilized as screening tests, much like the rapid screening test is being used as part of the current enhanced BSE surveillance program.

How is the training conducted for these tests?

USDA conducts training at the National Veterinary Services Laboratories (NVSL) in Ames, Iowa, and at NVSL's Foreign Animal Disease and Diagnostic Laboratory (FADDL) on Plum Island, New York, as well as in NAHLN facilities throughout the country. Each person that will be conducting the rapid diagnostic tests is trained and proficiency tested prior to conducting the test for official purposes.

USDA has also developed a "Train the Trainer" program to train NAHLN personnel to conduct—and then provide training to their colleagues on—the rapid assays for foot and mouth disease and classical swine fever. In April and May 2005, these training classes were convened at laboratories in Davis, California; Athens, Georgia; College Station, Texas; and Madison, Wisconsin.

Have or will similar tests be developed for plant disease?

Similar assays have been developed for plant diseases. These tests are directed to APHIS' Center for Plant Health Science and Technology in Raleigh, North Carolina, for evaluation. Any necessary modifications are then made to ensure the tests are ready for use in the field. If it is appropriate, the test would then be distributed to partners through the National Plant Diagnostic Network and the State Departments of Agriculture for screening purposes. Any confirmatory testing would be done at CPHST.

Questions For the Record
Senate Agriculture, Nutrition and Forestry Committee
"Bio-Security Preparedness and Efforts to Address Agro-Terrorism Threats"
July 20, 2005
Dr. Maureen McCarthy

Questions from Senator Ken Salazar

As you .are well aware, following the attacks of September 11th, the roles and responsibilities of federal agencies to protect against agro-terrorism were modified. This change resulted in the Department of Homeland Security (DHS) becoming the chief coordinating agency to protect the U.S. from agro-terrorist attacks.

Specifically, most of USDA's responsibility for conducting agricultural import inspections was transferred to DHS. In addition, about 3,200 inspector positions were transferred from USDA's

Plant Protection and Quarantine Unit to DHS. I understand that the General Accounting Office (GAO) has done a report on these changes from USDA to DHS and have found that several important challenges remain.

For example, obviously, the most effective way to control the spread of foreign animal diseases is to be able to quickly identify the disease at the border. According to GAO's findings, over the past two years agricultural inspections at ports of entry have declined while imports have increased. I am extremely concerned about this apparent drop in our first line of defense. I understand that there are vacancies for agricultural inspectors as well as a lack of training for U.S. veterinarians who are at the border to recognize diseased animals.

Furthermore, I understand that DHS inspectors often check through agricultural goods and, if they find something that is questionable, will quarantine the item until USDA inspectors get to the quarantine site. At a busy port of entry, time is of the essence especially in regards to agro-terrorism when an animal or plant disease could potentially be contagious, and it is essential that enough trained inspectors are in place.

What is being done to address this problem? According to the GAO report, you had planned to hire an additional 500 agricultural specialists - have those hires been made? Is 500 enough?

Response: At the end of FY04, CBP had 1,442 Agriculture Specialists on-board at the Ports of Entry. The goal has been to hire 500 employees to meet the on board staff of 1,872 by the end of FY05. Based upon current hiring projections CBP will meet the 1,872 Agriculture Specialists planned to be on board.

CBP will continue to hire additional Agriculture Specialists to match attrition. CBP will continue to assess the need for additional CBPAS based on varying risk and increasing workload. Based on a FY04 risk assessment, CBP may need to augment the 1872 figure.

CBP enforces USDA requirements on animal products at the ports of entry. Agriculture entry requirements and clearance are based on country, commodity, and foreign country disease status review, the presence of authentic and required foreign certificates and/or permits and verification of intact seals. Live animals are referred to USDA Veterinarians for examination.

Per the HS ACT, (and Memorandum of Agreement) USDA is responsible for issuing regulations, guidelines and procedures which CBP enforces. CBP keeps in regular contact with USDA per any discrepancies related to animal products or live animals as per the guidelines. CBP and USDA mutually developed training for CBP Agriculture Specialists to provide port of entry clearances as required.

What are USDA and DHS doing to increase the number and quality of agricultural inspections at points of entry?

To increase the value of referral, CBP is developing cross-training programs for CBP Officers on basic agriculture procedures for the land border, mail, cargo, maritime, and air passenger pathways. This training will allow CBP Officers to be a "force multiplier" by providing an extra set of eyes and ears to help detect more agricultural contraband and pests.

The Department plans to improve agricultural targeting to make more interceptions of pests and diseases. The assignment of Agricultural Specialists to the Advance Targeting Units (ATU) will greatly enhance the ability of DHS to more effectively target passengers and commodities at all the POEs. "Smarter" targeting will increase the number of interceptions by focusing on the people and commodities of greater risk. A number of Agricultural Specialists have already received the ATS targeting training necessary to be part of an ATU team.

As stated above, DHS has developed and delivered ATS training aimed solely at Agricultural Specialists. Three classes were completed by August 2005. ATS training for Agricultural Specialists in air cargo and land border POEs is slated to be completed by the end of FY 2006. As DHS targets higher risk commodities, it is unnecessary to keep pace with the number of inspections of low risk or random targets. Comparing the number of interceptions for the first three quarters of FY 2004 versus the same period in FY 2005, maritime cargo interceptions have risen twenty six percent.

In addition to the basic training, CBP is working with USDA to develop more specialized training at the ports of entry to increase the number of quality interceptions. This training will be based on local risk and pest pathways and agricultural commodities that are unique to the port. We are encouraging USDA and state cooperation within port pest risk committees to identify risk and pathways of concern.

USDA and DHS have entered into a Joint Agency Quality Assurance Plan (JAQAP) and have agreed to conduct joint quality assurance reviews of ports of entry (POE). This joint program is intended to study the performance of the agricultural mission under DHS and identify the best business practices of individual ports. If the JAQAP does a port review and finds a decline in inspections, the reasons for a port's declining inspections will be explored and actions to improve the port's performance will be recommended. This program is part of the overall agreement between the two agencies.

The Joint Teams' first review was in December 2004. In FY 2005, the Joint Team will have conducted four port reviews. Six more port reviews are expected to take place during the next calendar year. These cooperative efforts will identify weaknesses in the port's agricultural operations and suggest areas and ways to address those areas of concern.

The Department also plans to increase hiring of Agriculture specialist and Agriculture supervisors. In November 2004, DHS advertised 129 government-wide agricultural specialist positions. In addition, DHS approved 20 training classes for new officers that began in the summer of 2004 with 14 being in FY05 training 504 new Agricultural specialist and 6 in FY06 training 216 new specialist. Based on the scheduling of classes this means 720 new Agricultural

Specialist will pass the New Officer Training (NOT) and working at Post of Entry by February 2006.

In addition to new officers, DHS has identified the need to replace and increase the number of agricultural supervisors. The Department began issuing vacancy announcements for new agricultural supervisors during the week of February 7, 2005. The added supervisors will enhance the DHS agricultural inspection infrastructure as the number of specialists and their workloads increase.

How effective are these inspections and what are they looking for? Is money better spent on response rather than detection?

Response: The inspections presently being done and the expected increased inspections will be as effective, if not more, than the inspections done within USDA. The Commissioner's initiative, "One Face at the Border", adds additional officers to looking for and addressing agricultural concerns. CBP is convinced that the number of inspections will definitely increase to new levels.

As for the subject of such inspections, CBP Agricultural Specialists are looking for the same animal and plant pests that they were under USDA. Agricultural inspections cover both regulated and prohibited items. Agricultural Specialists are also on the watch for any hitchhiking pests, new species of insects not indigenous to the US and evidence of plant diseases. Moreover, the Agricultural Specialists are tasked with ensuring the proper entry of meat and animal by-products.

Detection is a vital part of the agricultural defenses of this nation. CBP must do everything possible to deter the introduction of the exotic pests and diseases. Some diseases and pests are so virulent and invasive respectively that there would be a very small window of opportunity for effective response with early field detection.556

Do current DHS inspectors have any sort of agricultural training and if so, how much?

CBP Agriculture Specialist (CBPAS) receive a pre-academy, academy, and a post academy (or in-port) training once the return from basic academy. The basic academy portion of the CBP Agriculture Specialist training takes place at the USDA Professional Development Center located in Frederick, Maryland. Currently, the schedule provides for forty-six (46) class days of training. This basic academy was designed in conjunction with USDA and is more academically rigorous than before the merger.

U.S. Customs and Border Protection (CBP) Officers have received agricultural training via a module entitled Agriculture Fundamentals (TRAEN # 074001). That module was created to increase the awareness and knowledge of the CBP Officer in the agricultural arena and set the foundation for the subsequent, more intensive agricultural training. The module was mandatory

for all CBP Officers that transferred from US Customs, US Immigration & Naturalization Service, and is required for all new hire CBP Agriculture Specialists.

For new hire CBP Officers, a sixteen-hour module is delivered by USDA instructors at the FLETC as part of their Basic Academy training regimen.

As part of their training regimen, the NAT/CET teams and Mobile Response Teams have also received instruction on agricultural bioterroism, safeguarding procedures, wood packing material concerns, prohibited contaminants, and compliance agreements.

A training segment that included an Agricultural Bioterrorism video (TRAEN #216001) was required viewing by all CBP field personnel.

CBP is developing extensive cross-training for CBP Officers on basic agriculture procedures for the land border, mail, cargo, maritime, and air passenger pathways to increase the value of referrals. This training will allow CBP Officers to be a "force multiplier", that extra set of eyes and ears to help detect more agricultural contraband and pests.

CBP has also developed and given a two-week Advanced Targeting Systems (ATS) program for the sea environment for Agriculture Specialists. The first class of eighteen participants was held at the Port of Baltimore in February 2005; the second class convened in Long Beach and the third class met in Baltimore.

Additionally, a course for ATS targeting of passengers for Agriculture Specialists is being developed and will be delivered by the end of this year.

2. It is my understanding that since September 11, we have worked to expand our agricultural laboratories and diagnostic infrastructure. In addition, several of our existing facilities have been upgraded in order to better respond to agro-terrorism. That being said, to date, there are only several BSL-4 (the highest level of secure labs in the U.S.) across the country.

With the recent necessity to send BSE samples to England for further testing and ongoing concerns with the potential of an agro-terrorist attack, do we need additional or upgraded BSL-4 facilities?

Response: With respect to the specific question of BSE testing, as USDA Deputy Secretary Conner stated in his testimony, the U.S. BSE samples were referred to the international reference laboratory at Weybridge (U.K.) in light of their significant technical experience gained in analysis of samples during the BSE outbreak in the U.K.

The handling of BSE samples from domestic animals does not require BSL-4 facilities.

On the broader question of BSL-4 facilities, there are currently no agricultural BSL-4 facilities in the U.S. HSPD-9 has tasked USDA and DHS to jointly explore potential needs for such

facilities, and to develop a plan to address those needs. DHS is currently working with USDA on this, and the inclusion of such a capability is one of the options being explored in the current conceptual design study for a National Bio and Agrodefense Facility (NBAF; see also Q02685 above).

How many BSL-3 laboratories are there in the U.S. and where?

Response: In addition to the PIADC (Greenport, NY), the nation's major Federal BSL-3 facilities for the study of animal diseases include the USDA facilities at the National Animal Disease Center (Ames, IA), Southeast Poultry Laboratory (Athens, GA), and Arthropod-Borne Animal Diseases Research Laboratory (Laramie, WY).

Several universities have now established BSL-3 capability, and there are numerous BSL-3 laboratories for the study of pathogens of public health concern, including those recently funded by DHHS bio-defense programs.

The June, 2005, report, "Survey for Determining the Location, Capacity, and Status of Existing and Operating BSL-3 Laboratory Facilities within the United States" identified 277 BSL-3 facilities in the U.S. Specific locations are listed in the report which is available at http://www2.niaid.nih.gov/Biodefense/PDF/BSL3_survey.pdf

As you know, several Federal agencies have begun to stockpile vaccines that would fight foreign animal disease. Unfortunately, currently, not only does the U.S. only stockpile one vaccine - Foot and Mouth Disease - but also, should there be an animal disease outbreak, these agencies would not be able to distribute vaccines because the strains of the vaccines that we do have would need to be sent to the United Kingdom to be activated before use. According to the GAO report, USDA officials have started a steering committee to address the costs and benefits of developing ready-to-use vaccines that can be deployed quickly to combat animal disease.

What is the status of this steering committee? Have the met, and if so, can you share any of their findings with us so far?

Response: The operational and policy issues associated with these questions are the mission responsibility of USDA APHIS as mostly recently stated in HSPD-9.

What is the sequence of events that needs to take place in order for DHS and USDA to authorize use of vaccines?

Response: The operational and policy issues associated with these questions are the mission responsibility of USDA APHIS as mostly recently stated in HSPD-9.

What are the costs of delaying the decision-making process? What steps could be taken to streamline this process?

Questions For the Record
Senate Agriculture, Nutrition and Forestry Committee
"Bio-Security Preparedness and Efforts to Address Agro-Terrorism Threats"
July 20, 2005
Dr. Maureen McCarthy

Response: The operational and policy issues associated with these questions are the mission responsibility of USDA APHIS as mostly recently stated in HSPD-9.

I understand that there is currently research being conducted to develop a rapid diagnostic tool to be used at ports of entry or at the site of an outbreak. This would allow inspectors almost instantaneous diagnosis of a disease.

What are the obstacles to deploying rapid diagnostic tools at the site of an outbreak?

Response: The operational and policy issues associated with these questions are the mission responsibilities of DHS and USDA APHIS. DHS, in consultation with USDA, determines whether or not to conduct active surveillance for agricultural pathogens at borders and other points of entry prior to known outbreaks, and USDA APHIS determines whether or not to use field-deployable assays during response to an outbreak. As part of the joint DHS-USDA strategy, a need for a FMD pen-side diagnostic was identified. The protocols for the use of such a test would be under the control of USDA APHIS. The National Center for Foreign Animal and Zoonotic Disease Defense currently has a project in collaboration with the PIADC to develop a FMD pen-side test.

What could we realistically accomplish with the resources we have now?

Response: A response capability already exists and DHS continues to work with USDA and other federal agencies to develop enhanced capabilities to manage the national response to threats to agriculture and our food supply. This includes veterinary countermeasures and diagnostics, basic and applied research, bio-surveillance communication, and better techniques to identify high risk transactions at the border.

Questions Submitted by Senator Salazar

According to the GAO report, you had planned to hire an additional 500 agricultural specialists—have those hires been made? Is 500 enough?

USDA defers to the Department of Homeland Security (DHS) on this question.

What are USDA and DHS doing to increase the number and quality of agricultural inspections at points of entry?

DHS' Bureau of Customs and Border Protection has control over the frequency of port-of-entry inspections for agricultural commodities, and is in the best position to answer this question.

We would add, however, that USDA and DHS, in cooperation, have developed a quality assurance program that helps ensure the high quality of agricultural inspection at points of entry into the United States. The quality assurance program is conducted by reviewers from both DHS' Customs and Border Protection and USDA's Animal and Plant Health Inspection Service (APHIS). This group visits ports of entry to examine best practices and any potential deficiencies related to agriculture inspections. The group then issues a report outlining what operations are working effectively at the port, as well as what could be improved. The quality assurance program has been successful and continues to evolve to meet the needs of both agencies.

How effective are these inspections and what are they looking for? Is money better spent on response rather than detection?

While visual inspection at the ports of entry is an essential part of the import process, it has limitations and makes it necessary to have a strong system of control in place for imported products prior to their arrival at the ports. APHIS places a heavy emphasis on prevention by ensuring that the risk of pests or diseases entering the United States is mitigated before products arrive at ports of entry. Specifically, any agricultural commodity that is to enter the United States must be evaluated to determine its potential risk. High-risk commodities will require treatment (such as fumigation) either at the product's origin or upon arrival to ensure that any pests are destroyed. Other commodities that pose a risk undergo a system of overlapping risk mitigation measures. These protection measures help guarantee that the lowest risk product possible is presented for visual inspection at the ports of entry.

APHIS' experiences with foreign pests such as the Asian longhorned beetle and the emerald ash borer highlight the price of even regional response efforts. The fiscal year 2006 budget request includes $47.6 million to combat these pests alone. Detecting and preventing pests and diseases prior to entry are certainly more cost-effective and are therefore the focus of APHIS' efforts prior to point of entry inspections conducted by DHS.

What is USDA's progress in making foreign animal disease training a pre-requisite for USDA veterinary accreditation?

USDA is making good progress in revising the requirements for the National Veterinary Accreditation Program (NVAP). We fully recognize that because of the increased threat posed to animal and human health today from exotic animal diseases, accredited veterinarians must increase their knowledge of, and vigilance for, emerging and exotic animal disease conditions. Once finalized, the new NVAP will emphasize the lifetime education of participating accredited veterinarians, to keep them current on the latest domestic and international animal health events. Training modules designed specifically for accredited veterinarians will be available that provide the latest information on the transmission, recognition, and reporting of exotic diseases; emerging disease concerns; and evolving accreditation program policy and procedures. These revisions will strengthen the knowledge base of the national community of accredited veterinarians, and better integrate these veterinarians into a national animal health network intent on protecting animal and human health in the United States.

Do current DHS inspectors have any sort of agricultural training and if so, how much?

There are two types of DHS inspectors, Agricultural Specialists and Customs and Border Protection officers. In 2002, when USDA's Agricultural Quarantine Inspection program was transferred to DHS, responsibility for the training of the Agriculture Specialists remained with USDA. Consequently, Agricultural Specialists undergo 8 weeks of

agricultural training, just as they did when they were employed by USDA. The training covers numerous areas of importance, including animal and plant health regulations, pest interception, and certification reviews. Agriculture Specialists also undergo 2 weeks of training on law enforcement procedures.

Customs and Border Protection Officers also receive agricultural training, in the form of agricultural training modules. This training is carried out by DHS, and officials there are in the best position to provide more information in this regard.

With the recent necessity to send BSE samples to England for further testing and the ongoing concerns with the potential of an agroterrorist attack, do we need additional or upgraded BSL-4 facilities? How many BSL-4 laboratories are there in the U.S. and where?

We'd like to first clarify that the recent situation involving the further testing of a sample for BSE at the Veterinary Laboratories Agency (VLA) in Weybridge, England, was not the result of an inadequate biosafety level at USDA's National Veterinary Services Laboratories in Ames, Iowa. Rather, as the international reference laboratory for BSE, VLA has much more experience interpreting test results from animals with low levels of infection, as was the case with the 12 year old animal from Texas.

At this time, USDA does not have any BSL-4 laboratories. The United States only has 3 BSL-4 laboratories—a U.S. Centers for Disease Control and Prevention laboratory in Atlanta, Georgia, a U.S. Department of Defense laboratory in Fort Detrick, Maryland, and the Southwest Foundation for Biomedical Research in San Antonio, Texas. These laboratories focus efforts exclusively on human diseases. There is no BSL-4 capability in the United States for livestock diseases that are zoonotic or emerging (and therefore unknown in their danger to humans).

BSL-3 space, however, is adequate for testing many agroterrorism agents, and BSL-3 Agriculture (BSL-3Ag) space is appropriate for livestock studies with these agents. USDA's National Centers for Animal Health in Ames, Iowa, currently includes 700 net square feet of BSL-3 space for studying anthrax, tularemia, and plague. In addition, there is 2,900 net square feet for BSE work. The high containment large animal facility, estimated for completion in mid-2007, will include approximately 46,100 net square feet of BSL-3 Ag space for diagnostics, training, reagent production, and research activities. The next phase of laboratory construction will also include 1,840 net square feet of BSL-3 space for vaccine evaluation; 9,090 net square feet for brucella and bovine tuberculosis reagent production; 20,400 net square feet for viral diagnostics; and 2,300 net square feet for brucella and bovine tuberculosis research.

While targeted animal disease surveillance testing can be conducted in BSL-2 laboratory space, BSL-3 space is required for testing samples during a disease outbreak to prevent additional spread of the disease. The National Animal Health Laboratory Network (NAHLN) is currently in the process of assessing the existing BSL-3 space in the United States, and will complete this assessment in the near future. The amount of available

space is being overlaid with animal population densities as well as risk of incursion of disease, in order to generate a more complete picture of the country's potential needs in this regard.

According to the GAO report, USDA officials have started a steering committee to address the costs and benefits of developing ready-to-use vaccines that can be deployed quickly to combat animal disease. What is the status of this steering committee? Have they met, and if so, can you share any of their findings with us so far?

APHIS administers a National Veterinary Stockpile (NVS) for specific, high-threat foreign animal diseases. NVS is capable of maintaining vaccine for use in the United States in the event of a significant foreign animal disease outbreak. APHIS will use the NVS to consider and obtain "ready-to-use" vaccine product. The goal is for NVS to become one component of an overall response planning and recovery effort to provide the best possible protection against an attack on our agriculture and food system.

An NVS Steering Committee, which includes representatives from DHS and the Department of Health and Human Services, has been established as a recommending body to determine what is contained in the NVS. The NVS Steering Committee's charter charges the Committee to ensure that decisions regarding the composition, inventory, storage, deployment, use, and staffing of the NVS are based on the most current threat assessment, the most rigorous science available, the best predictive modeling possible, and the best expert advice.

The fiscal year 2006 budget proposes $8.12 million for APHIS to continue stockpiling FMD vaccines and supply NVS. APHIS has approved a position for a National Veterinary Stockpile Manager and efforts are underway to reduce delays in obtaining "ready-to-use" vaccine.

What is the sequence of events that needs to take place in order for DHS and USDA to authorize use of vaccines?

Using foot and mouth disease (FMD) as an example, USDA maintains foot and mouth disease (FMD) vaccine through the North American FMD Vaccine Bank (NAFMDVB). This Bank consists of viral antigen concentrate, the precursor to finished vaccine, and is maintained by agreement between the United States, Canada, and Mexico. Accordingly, the procedures established for the holding, maintenance, and deployment of FMD vaccine is set through formal agreement among the 3 countries. The decision to deploy FMD vaccine is the responsibility of the Chief Veterinary Officer of each country. For other diseases, such as avian influenza, the decision to vaccinate animals would be made by USDA on a case-by-case basis, weighing all of the pertinent factors, including international trade implications.

What are the costs of delaying the decision-making process? What steps could be taken to streamline this process?

FMD vaccines are not stored in a "ready-to-use" state because the vaccines are strain-specific and have a short shelf life. Replacing FMD in the form of a stockpile on a regular basis in quantities sufficient for large scale response would be very expensive. In addition, because there are several strains of the virus, it is impractical (and, again, exceedingly expensive) to maintain stockpiles for every one.

The Vaccine Bank antigens are stored in an unfinished state and have a very long shelf-life. The antigen contained in the Bank assures finished vaccine will meet safety, potency, efficacy and purity standards to produce vaccine acceptable for use in North America.

FMD vaccines are formulated in production facilities outside of the United States. The North American FMD Vaccine Bank holds the antigen precursor to the formulated "ready-to-use" vaccine. The formulation process takes a short time to complete and produce the "ready-to-use" vaccine. APHIS must ship banked antigen precursors for the intended vaccine overseas, where we currently have a contract with a FMD vaccine manufacturer, to be made into the "ready-to-use" vaccine. The contract calls for finished vaccine to be delivered to the United States within 3 days after the manufacturer receives the antigen concentrate.

During this time, it is essential to understand that there are other more effective methods of disease control that can be employed—including "stop movement" orders for animals, quarantines, and depopulation—to limit disease spread. In addition, during this time logistical preparations are made for vaccine delivery and administration.

As the General Accountability Office (GAO) report points out, the decision tree to use vaccine is complex. Vaccination crews must be selected, deployed, equipped, and directed within 24 hours in order for vaccine made available that quickly to be advantageous. Thus, FMD vaccine is one part of an overall response plan.

The GAO report suggests it would be prudent to have available FMD vaccine within 24 hours of an outbreak. While USDA does not disagree, with current technologies it will require more than that amount of time to determine the particular strain of FMD virus causing the infection. Again, it must be noted that it is time intensive to select, deploy, equip, and direct vaccination crews to administer vaccine in a manner that would be advantageous to disease containment and eradication.

What are the obstacles to deploying rapid diagnostic tools at the site of an outbreak?

The poor positive predictive value of even the best assays when disease prevalence is low means most positive test results will be false positives. For this reason, APHIS has been reluctant to utilize assays in the field, where follow-up tests cannot be readily completed.

After a disease introduction, however, the prevalence of the disease in an animal population is higher, and the positive predictive value of most existing tests is quite good, leading to fewer false positives. In those situations, it could be possible that USDA would deploy real-time PCR tests to the area in and around the site of a disease detection.

Validation of newly developed assays is always challenging, however. Generally speaking, the work is costly and time consuming, and, for a variety of reasons, it is often difficult to obtain necessary tissue samples from areas where the disease in question is endemic.

What could we realistically accomplish with the resources we have now?

In the event of a foreign animal disease detection in the United States, USDA would support emergency control, eradication, and surveillance efforts on the ground with the efforts of Federal laboratory personnel running screening tests for the disease in question. This would be followed by the emergency use of NAHLN laboratories running approved rapid assay tests. While the reporting and communications components of this cooperative effort are currently under development, it is likely that the protocols will be very similar to how the enhanced BSE surveillance program has been carried out over the last year.

At this time, the following are 2 important examples of the testing capacity at NAHLN facilities:

- Avian Influenza and Exotic Newcastle: Personnel from 36 State laboratories and NVSL have been trained and proficiency tested. The current testing capacity is 18,000 samples per day.
- BSE : Personnel from 7 State laboratories and NVSL are currently performing testing. The current testing capacity is 1,500 samples per day.

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