STATEMENT FOR THE RECORD

of

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Regarding a Hearing Entitled

"Reducing Threats to Our Nation's Agriculture: Authorizing the National Bio and Agro-defense Facility (NBAF)"

Before the
U.S. House of Representatives
Committee on Homeland Security
Subcommittee on Emerging Threats, Cybersecurity, and
Science and Technology

INTRODUCTION

Good afternoon, Chairman Langevin, Ranking Member McCaul, and distinguished members of the Subcommittee. I am pleased to appear before you today to discuss the Nation's critical need for the Department of Homeland Security's National Bio and Agro Defense Facility.

There is a need for a secure, state-of-the-art agriculture biocontainment facility that researches and diagnoses foreign animal and zoonotic diseases. Currently, there is only a limited research laboratory capacity in the Nation for large animal BioSafety Level -3 (BSL-3Ag) studies, and there is no BSL-4 research space for the study of threat agents that infect both large animals and humans. If the United States is to have the proper capability to rapidly identify and control outbreaks of high-threat foreign animal and zoonotic disease agents, whether natural or intentional, it must begin investing in additional biocontainment capacity and capability.

Numerous infectious animal diseases are present throughout the world that threaten the nation's public health, agriculture and economy. For example, recall the foot-and-mouth disease outbreak in the U.K. in 2001 and the catastrophic losses that this outbreak caused that nation, and from which it is still recovering now six years later. The economic loss was well into the billions, affecting agricultural industries but having a wider impact on other industries including tourism. The impact would be far greater in the U.S, with its much larger livestock population, larger herds, and extensive shipment across the country.

As evidenced by recent examples, including West Nile Fever and Avian Influenza, existing and emerging foreign animal and zoonotic diseases pose an immediate threat not only to our agricultural industry but also to our public health.

Realizing this threat, the President issued Homeland Security Presidential Directive 9: *Defense of the U.S. Agriculture and Food*. HSPD-9 requires the Secretaries of Agriculture and Homeland Security, Health and Human Services, and the Administrator of the Environmental Protection Agency to "develop a plan to provide safe, secure and state-of-the-art agricultural biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases" and further states that "The Secretaries of Homeland Security, Agriculture ... will accelerate and expand development of current and new countermeasures against intentional introduction or natural occurrence of catastrophic animal, plant and zoonotic diseases." As will be elaborated in the following sections, NBAF fulfills a critical role in meeting both these requirements and ensuring that the nation's public health, food and agriculture are protected for the next 50 years.

In pursuing NBAF, DHS will work closely with its partners in the United States Department of Agriculture under the same terms and spirit as it currently does at the Plum Island Animal Disease Center.

The Need for NBAF

For more than 50 years, the Plum Island Animal Disease Center (PIADC) has served as the nation's first defense against foreign animal diseases. However, the threats to the Nation's agriculture and public health have changed dramatically since the time of PIADC's establishment. These changes include the globalization of travel and trade, the broadened size and scope of U.S. livestock and agricultural industry, and now the threat of agro-terrorism. PIADC's research and diagnostic activities stem from its mission to protect U.S. animal industries and exports from deliberate or accidental introduction of foreign animal diseases. PIADC has been a leader in researching foreign animal diseases, developing diagnostics and vaccines to prevent and contain them, and training foreign animal disease diagnosticians to detect them. The Homeland Security Act of 2002 transferred the operations of PIADC to DHS. Since that time, the DHS Science & Technology Directorate has been working jointly with the United States Department of Agriculture's Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS) to meet the island's shared mission objectives.

However, despite significant investments in the facility's infrastructure, Plum Island Animal Disease Center is unable to fully meet the research and diagnostic capabilities required to address the threat of agro-terrorism. The available laboratory space at PIADC, especially the large animal holding laboratory space, is limiting the pace at which we can develop improved veterinary countermeasures. The joint USDA-DHS team has made significant progress in developing next-generation vaccines for foot-and-mouth disease. The path forward for such state-of-the art vaccines includes taking these discoveries through developmental and testing phases for licensure necessary for inclusion in the National Veterinary Stockpile and for eventual use by first responders. However, the limited animal testing space at PIADC is limiting the number of vaccine trials that can be conducted and drastically extending the time frame to complete these studies. Additionally, because of capacity and biocontainment constraints, PIADC concentrates on research and diagnostic activities for only a subset of the highest-consequence foreign animal disease and cannot facilitate expanded research into other high priority foreign animal disease and emerging threats of concern.

Additionally, BSL-4 work cannot be done at PIADC. Thus, the nation lacks a facility to adequately address high-consequence zoonotic diseases that infect both large animals and humans. The impact of disease agents, such as Rift Valley Fever, Nipah, and Hendra, underscore the growing threat posed by emerging zoonotic diseases and the need to establish better facilities to study them.

To address these limitations, the planned NBAF will provide the infrastructure necessary to research and develop diagnostics for, and countermeasures to, high-consequence biological threats involving foreign animal and zoonotic diseases by:

- Providing state-of-the art biocontainment laboratories for development, test and evaluation of countermeasures for foreign animal and zoonotic diseases to support their inclusion in the National Veterinary Stockpile;
- Integrating those aspects of animal and public health research that are key to fulfilling that mission;
- Continuing to meet evolving needs in defending against agro-terrorism threats over the next five decades.

Plum Island Animal Disease Center's capability is a critical national asset and essential to protecting the U.S. agriculture economy and food supply. No other facility now exists in this country to perform this research. However, due to its age, location and outdated design, PIADC does not meet all of the nation's current needs. The planned NBAF will enable us to fully meet the challenges of intentional or unintentional introduction of a foreign animal disease that could threaten public health and the food supply over the next 50 years.

The Scope of NBAF

NBAF is being designed to provide the Nation with the "safe, secure, and state-of-the-art agriculture biocontainment laboratories" (HSPD-9) needed to develop countermeasures to current, emerging and future foreign animal and zoonotic diseases. The facility design will enable concurrent development of multiple priority vaccine candidates. It will also meet the shared interagency mission objectives of a successful agro-defense strategy, including:

- basic research on how an organism infects an animal and how the disease is transmitted from animal to animal;
- identification of 'lead candidates' for new vaccines and antivirals and novel delivery systems to better facilitate response actions;
- pilot lot production and proof-of-concept testing of those lead candidates;
- the development of molecular diagnostics to characterize the efficacy of the new countermeasures;
- clinical testing and evaluation of the countermeasures to support licensure by the USDA Center for Veterinary Biologics and inclusion in the National Veterinary Stockpile;
- maintain a vaccine bank that contains a secure inventory of antigens that would be used to formulate a vaccine in the event of an outbreak;
- develop and test diagnostics to rapidly identify, characterize, and control outbreaks;
- train veterinarians, giving them first hand experience in recognizing and diagnosing high consequence foreign animal diseases and thereby establishing a clinical capability for rapid response throughout the U.S.

DHS, in close coordination with USDA, is actively engaged in the definition of these program areas and the conceptual design of facility aspects to best support them. Additionally, USDA personnel are active participants in the NBAF site selection process. The conceptual design is independent of the site selected and will ensure that the NBAF's research requirements will be met. Such a state-of-the-art facility will synergize with existing veterinary, medical and public health, and agriculture programs and will help attract, train and retain future generations of researchers, technicians, diagnosticians, veterinary and medical personnel.

DHS has begun taking the steps to make this vision a reality. In January of 2006 DHS issued a notice of request for Expressions of Interest (EOI) for potential sites for the NBAF in the Federal Register and received 29 submissions from consortia in 21 states. An interagency review committee (DHS, USDA, HHS and DoD) evaluated the site proposals using four major sets of criteria which had been published in the EOI notice of request:

- Site proximity to Research Capabilities that can be linked to NBAF mission requirements
- Site proximity to a skilled Workforce to support NBAF mission requirements
- Acquisition/Construction/Operations; and
- Community Acceptance

Based on this initial evaluation, 12 consortia in 11 states were asked to submit additional information on 17 sites. That information is currently under review. In addition, the review team and the DHS Under Secretary for Science and Technology are visiting each of the sites for further evaluation. Following the site visits, a small number of sites will be selected for inclusion in the Environmental Impact Statement (EIS). This selection will be completed by June 2007. The final site selection will be determined following completion of the EIS.

Key milestones and anticipated dates in this process are summarized below:

 Additional information due 	February, 2007
 Conduct reviews 	March, 2007
• Site visits	April- May, 2007
 Issue Notice of Intent (NOI) announcing sites 	June, 2007
selected for evaluation in the EIS	
• Begin EIS	July, 2007
 Complete EIS; announce site selection 	October, 2008
 Begin detailed design 	November, 2008
Begin construction	2010
 Facility operational 	2013 - 2014

Conclusion

In summary, the planned NBAF will play a crucial role in protecting the Nation against current and future foreign animal and zoonotic diseases, whether naturally or intentionally introduced. The list of such high priority diseases is already long and growing. Plum Island has been doing an excellent job in the defense against foreign animal disease threats – but the age of its facilities and its limited capacity is pacing the development of needed countermeasures. Further, there are no facilities in the Nation to fully address those zoonotic diseases that affect both large animals and humans and attract the scientists, technicians, researchers, veterinarians and medical personnel needed to defend against current and future threats for the next 30-50 years. Therefore, DHS is committed to making the planned NBAF, as the next generation capability to support our partners in ARS and APHIS, a reality.

SUPPLEMENTAL SHEET – FOLLOW-UP ADDRESS:

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