

STATEMENT FOR THE RECORD

of

**The Honorable Jay M. Cohen
Under Secretary
Science & Technology Directorate
Department of Homeland Security**

National Bio- and Agro-Defense Facility (NBAF) Decision Process

**House Energy and Commerce Committee
Subcommittee on Oversight and Investigations**

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INTRODUCTION AND BACKGROUND

Good morning Chairman Stupak and Ranking Member Whitfield. I am pleased to appear before you today to discuss the Department of Homeland Security's (DHS) and Department of Agriculture's (USDA) proposed National Bio- and Agro-Defense Facility (NBAF). As you are aware, our Nation's animal health, agriculture, food supply, and economy are potentially threatened by numerous infectious disease agents, which are present throughout the world. Approximately 70-80 percent of emerging pathogens are zoonotic agents. These are disease agents capable of passing between animals and people.

DHS's Science & Technology Directorate focuses on the development of efficacious vaccines, therapeutics, and diagnostics to counter and mitigate these catastrophic agents. This effort requires a state-of-the-art agriculture bio-containment facility that allows safe, secure conduct of mission-directed scientific research, development, test, and evaluation (RDT&E) activities. This effort requires a secure, state-of-the-art agriculture bio-containment facility that allows scientists to perform their work in an environment where they can be isolated from the disease agents and where these agents can be isolated from the public and animal populations. Currently, the Nation's capacity is limited to only a few Biosafety Level -3 AG (BSL-3Ag) facilities, and there is no Biosafety Level 4 (BSL-4) research capacity to study threat agents that infect both large animals and humans, using large animal models. If the United States is to have adequate capability to rapidly identify and control outbreaks of high-threat foreign animal and zoonotic disease agents, whether natural or intentional, we must begin investing in sufficient bio-containment capacity and capability.

This investment is critical to DHS and USDA's Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS). ARS is the primary intramural science research agency of USDA, operating a network of over 100 research laboratories across the nation that work on all aspects of agricultural science. APHIS is responsible for safeguarding U.S. agricultural health from foreign pests and diseases of plants and animals.

To continue providing U.S. agriculture with the latest research and technological services, as well as world-class approaches to agricultural health safeguarding and foreign-animal disease diagnostics, ARS and APHIS need additional space and upgraded biosecurity measures to continue work

on those diseases that pose the greatest risk to U.S. livestock industries, and those that can also be transmitted to humans (zoonotic diseases). The state of the current facility has created a backlog of needed space for important experiments, diagnostics, and training efforts.

As an example of the potential consequences of a significant disease outbreak, recall the catastrophic losses from the 2001 foot-and-mouth disease (FMD) outbreak in the U.K. The economic loss reached well into the billions of dollars, directly affecting agricultural industries, and the outbreak had an even wider impact on tourism and other commerce. If the U.S. were faced with an equivalent outbreak, the impact could be far greater since the U.S. production is 14 (or more) times larger than that of the U.K. The U.S. uses concentrated animal feeding operations (CAFO) for many of its operational types of rearing, such as cattle and swine. This concentrates our vulnerability into even higher numbers.

In an effort to clarify and understand our R&D capacity and capability requirements, the White House's Office of Science and Technology Policy (OSTP) convened in 2003 a Blue Ribbon Panel on the Threat of Biological Terrorism Directed against Livestock, comprised of nationally and internationally recognized science leaders from multiple government, academic, and industrial institutions. The OSTP Blue Ribbon Panel report states that

“... new investment in infrastructure will be required to conduct these types of research and develop new technologies. In particular, lack of infrastructure places severe constraints on our ability to perform research, and develop technologies, involving pathogens classified as BSL-3 or above. Furthermore, the United States has no BSL-4 capable facility for studies in large livestock species.”

Emerging diseases represent a threat to our Nation's livestock and agricultural economy. Additionally, emerging diseases that are potentially zoonotic in nature reflect an even greater threat. An example of such emergent diseases are the Nipah and Hendra viruses. When the Nipah and Hendra viruses emerged in the 1990s, little was known about the mode of virus transmission, the duration of the virus' incubation period, or why certain hosts (both animal and human) died whereas others did not. Both the

Nipah and Hendra viruses, as well as unknown but emerging diseases, are reasons a BSL-4 large animal capable facility is needed.

To illustrate how a foreign pathogen can quickly become established here, and have significant effects, consider West Nile Virus, a mosquito-borne disease that had never been in the United States until 1999. Since then, there have been thousands of human cases of the disease, and hundreds of fatalities. In 2003 alone, CDC reported 9862 human cases of the disease, with 264 fatalities.

West Nile Virus is mild in comparison to Rift Valley Fever (RVF), which is also a mosquito-borne disease. In a 2007 report, Rift Valley Fever was identified as a “Top Priority Disease” by the National Science and Technology Council’s (NSTC) Foreign Animal Disease Threats (FADT) Subcommittee. In animal hosts, Rift Valley Fever causes abortion, loss of condition, loss of young animals, loss of production in cattle, sheep and goats, and mass deaths of these animals. (One of the most notable episodes occurred in Kenya in 1950-1951, resulting in the death of an estimated 100,000 sheep.) The most severe impact is observed in pregnant livestock infected with the disease, resulting in abortion of virtually 100% of fetuses. Rift Valley Fever also has a high fatality rate in puppies and kittens and spreads through various routes from domestic animals to humans. (The CDC has stated that approximately 1 percent of humans infected by Rift Valley Fever would die; however, a 2007 outbreak of Rift Valley Fever in Sudan caused over 600 human cases of the disease, with over 200 fatalities. The number of fatalities far exceeds the CDC estimate.)

Presently our capabilities to research and to develop countermeasures against emerging diseases, Rift Valley Fever, and other large animal-associated disease with zoonotic potential are hindered by the absence of large-animal, BSL-4 laboratory space. Researching the disease and developing diagnostic tests and countermeasures, requires that researchers be protected in BSL-4 laboratory space, which would also protect the public and the environment from exposure. If sufficient vaccines were available to protect researchers against Rift Valley Fever, they could work with this virus in BSL-3 facilities, but because the limited amount of experimental vaccine is in a critically short supply that is almost depleted and requires multiple injections, safe work with this virus must be done in BSL-4. Additionally, there are unknown and emerging diseases for which we have no vaccine protection or other countermeasure protection available to our researchers. When researchers on

the front lines receive samples that contain an unknown infectious agent, this agent must be handled in BSL 4 containment until the agent's properties are understood. We cannot ask our researchers working with uncharacterized diseases and livestock to operate without adequate protection. BSL-4 containment for livestock (large animals) is a much needed capability in this country.

On January 30, 2004, in recognition of the threat of agro terrorism, the growing need for countermeasures to protect the Nation's agriculture, and the limitations posed by the current Plum Island Animal Disease Center (PIADC), the President issued Homeland Security Presidential Directive 9: "Defense of the United States Agriculture and Food." HSPD-9 requires the Secretaries of Agriculture and Homeland Security, Health and Human Services, as well as the Administrator of the Environmental Protection Agency to

"develop a plan to provide safe, secure and state-of-the-art agricultural bio-containment 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. The Secretary of Homeland Security will coordinate these activities."

The proposed NBAF would fill a critical gap in our national preparedness and response capabilities, meeting both these requirements and ensuring that the Nation's animal health, food supply, and agriculture are protected for the next 50 years.

The Need for NBAF

For more than 50 years, the PIADC and its expert staff have been the front line of the Nation's defense against foreign animal diseases. PIADC's capability is a critical national asset and essential to protecting the U.S.

agriculture economy and food supply. No other facility currently exists in this country to perform this function. PIADC's research and diagnostic activities are an outgrowth of its mission to protect U.S. animal industries and imports and exports from the deliberate or accidental introduction of foreign animal diseases. PIADC has been a leader in researching foreign animal diseases, developing diagnostics and countermeasures (such as vaccines to prevent and contain these diseases), as well as training foreign animal disease diagnosticians to recognize diseases, collect appropriate diagnostic samples, and report disease. The Homeland Security Act of 2002 transferred the Plum Island facility to DHS to align with the DHS homeland security mission. Since that time, the DHS Science & Technology Directorate has been working jointly with ARS and APHIS to meet PIADC's shared mission objectives.

The working relationship between the agencies since the transfer of PIADC to DHS has been outstanding. Similar to the management of programs prior to the transfer, the agencies at PIADC operate under a Board of Directors and Senior Leadership Group structure that facilitates decision making regarding facility operations and policies, and also enables the Directors to focus on accomplishing their agency-specific missions and goals. Following the transfer of management of PIADC to DHS, USDA-APHIS, USDA-ARS, and DHS signed an interagency agreement that established this management structure and clarified the roles and responsibilities of each agency located at PIADC. The interagency agreement is reviewed each year and modifications made as necessary. I envision this same kind of very successful management structure to continue at the proposed NBAF.

The need for agro-defense has grown significantly over the past 50 years, fueled by a growth in the Nation's livestock industry, increased globalization of markets, increased air travel, and the serious threat of agro-terrorism. The current Plum Island facility is too small to meet the needs of the Nation and its dated facilities are increasingly costly to maintain. The facility's lack of large-animal holding space is particularly limiting. The inadequate space constrains our ability to develop countermeasures in a timely fashion, thereby leaving the Nation more vulnerable. These constraints limit us to the development of one countermeasure for one disease per year.

The currently available FMD vaccine requires 3-4 weeks of lead time to move from virus stocks to useable vaccine formulation and we must first identify the specific strain/serotype in order to formulate a useful vaccine.

For instance, a new generation vaccine against foot and mouth disease, deployable in 24 hours, requires the development of 10 to 14 separate vaccines to cover each of the major serotypes and sub-serotypes of the disease. Beyond this, we need to develop next-generation countermeasures for FMD, advanced vaccines that provide cross-protection and similar countermeasures for Rift Valley Fever, Classical Swine Fever, and African Swine Fever, as well as, emerging diseases such as Nipah and Hendra viruses. Work with Nipah and Hendra viruses requires BSL-4 laboratory space because these diseases are lethal to both human and animals and have no known medical treatments. To prevent the potential tragedy these diseases represent, we need to be able to study and develop appropriate countermeasures. But, again, we must conduct this work in an environment that protects scientists, animal populations, and the public. There are no BSL-4 facilities capable of handling large animals in this country and no facilities capable of handling the necessary number of large animals. If history is a guide, other new diseases requiring BSL-4 laboratory space will emerge and will need to be addressed.

Since taking over operations of the PIADC facility in 2004, DHS has invested over \$80 M in corrective actions and facility upgrades based on the FY05 multi-year Corrective Action Plan Report to Congress. These projects are in five general areas: (1) security programs and systems; (2) information technology and communication systems; (3) environmental, health, and safety systems; (4) buildings, grounds, and infrastructure systems; and (5) administrative and management programs. Despite significant investments in the facility's infrastructure, Plum Island is unable to meet the research and diagnostic and training capabilities required to address the threat of agro-terrorism now and its capacity is certainly not adequate to meet future needs. The path forward for state-of-the art vaccines requires moving from scientific discoveries through developmental and testing phases for licensure necessary to include new vaccines in the National Veterinary Stockpile (the creation of which was mandated by HSPD-9) and for eventual use by first responders. Currently, because of capacity and bio-containment constraints, Plum Island concentrates on research and diagnostic activities for only a subset of the highest-consequence foreign animal diseases. The existing facilities at Plum Island cannot host expanded research into other high-priority foreign animal disease and emerging threats of concern.

Scope of NBAF

To address these limitations, the proposed NBAF would 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 bio-containment laboratories for development, testing, and evaluation of countermeasures (including vaccines and diagnostics) against foreign animal and zoonotic diseases and to support their inclusion in the National Veterinary Stockpile;
- Providing coordinated mission space for large animals. Other facilities do not work with livestock or do not have the capacity to incorporate foreign animal disease impacting livestock into mission space at both the BSL-3 and BSL-4 levels;
- Integrating animal and public health research to fulfill this mission; and
- Continuing to meet evolving needs in defending against agro-terrorism threats over the next five decades.

The proposed NBAF would enable us, over the next 50 years, to fully meet the challenges posed by the intentional or unintentional introduction of a foreign animal disease or diseases that could threaten the public health and the food supply. The facility design would enable concurrent development of multiple priority vaccine candidates, antivirals, and other countermeasures. It would also meet the shared interagency mission objectives of a successful agro-defense strategy, including:

- Performing basic research on how an organism infects an animal and how the disease is transmitted from animal to animal;
- Identifying 'lead candidates' for new vaccines and antivirals and novel delivery systems to better facilitate response actions;
- Testing of small pilot lots or batches of promising vaccines and antivirals developed at the facility;
- Developing molecular diagnostics to characterize the efficacy of the new countermeasures;
- Developing high-throughput diagnostic capability to cope with an influx of large numbers of samples that can be anticipated in the face of any outbreak;

- Providing clinical testing and evaluation of the countermeasures to support licensure by the USDA Center for Veterinary Biologics and inclusion in the National Veterinary Stockpile;
- Maintaining a vaccine bank that contains a secure inventory of antigens that would be used to formulate a vaccine in the event of an outbreak;
- Providing support and reference laboratory functions to the expanding National Animal Health Laboratory Network;
- Developing and validating new diagnostics to rapidly identify, characterize, and control outbreaks of emerging diseases; and
- Training veterinarians by 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. A state-of-the-art BSL-3 and BSL-4 facility would synergize with existing veterinary, public health, and agriculture programs and would help attract, train, and retain future generations of researchers, technicians, diagnosticians, and veterinarians. The proposed NBAF would fulfill the above requirements by establishing a state of the art BSL-3 and BSL-4 laboratory with the capacity and capability to rapidly identify and control outbreaks of high-threat/high consequence foreign animal, emerging, and zoonotic disease agents.

NBAF Site Selection Process

In Fiscal Year 2006, Congress appropriated money for site selection and other pre-construction activities for the NBAF. DHS developed a site selection process because Congress did not designate a specific site upon which to build and construct NBAF. Based upon concerns about the adequacy of PIADC to support current and future needs, as well as local opposition to building a bio-containment facility with BSL-4 laboratory space at the Plum Island facility, DHS determined it would be appropriate to explore additional site alternatives on the mainland. The site selection process was used to solicit and evaluate proposals from consortiums across the country interested in hosting the NBAF. The site selection process began with DHS's publication of a public notice soliciting expressions of interest

(EOI) for Potential Sites for the NBAF in the Federal Business Opportunities on January 17, 2006 and the Federal Register on January 19, 2006. DHS received 29 EOIs by the March 31, 2006 due date stated in the Public Notice Soliciting EOIs. DHS conducted an initial evaluation of the 29 EOIs, using the 4 evaluation criteria set forth in the Public Notice Soliciting EOIs.

DHS and USDA jointly developed the evaluation criteria used to evaluate and narrow the selection to a small number of sites. The evaluation criteria included site proximity to research capabilities that could be linked to the NBAF mission requirements, site proximity to a skilled workforce with applicable expertise, acquisition/construction/operations, and community acceptance. A team of interagency Federal employees evaluated the EOI submissions, assessing their strengths, weaknesses, and deficiencies against the four evaluation criteria. At this First Round stage, sites were eliminated from further consideration due to weaknesses and/or deficiencies with respect to the evaluation criteria, including lack of proximity to existing BSL-3 or BSL-4 research programs that could be linked to NBAF mission requirements; difficulty in demonstrating ability to attract world-class researchers and scientists or skilled technical workforce with necessary experience; insufficient community support for siting of the NBAF; and insufficient feasibility for infrastructure build-out or other siting difficulties.

When I was sworn in on August 8, 2006, DHS had already narrowed the candidate sites to 18 sites, proposed by 12 consortia, for further review. I requested that the consortia provide additional information, limited to the broader categories of information falling within the originally published evaluation criteria in DHS's Public Notice soliciting EOI. In December 2006, DHS sent Additional Information Request letters to the consortia proposing the 18 remaining sites. In the December 2006 letters, DHS also communicated its preference for certain evaluation criteria which would be considered by the Federal employee evaluation committee in the second phase of DHS's site selection process. These DHS preferences were that:

- (1) the proposed site be located in a comprehensive research community with existing research programs in areas related to NBAF mission requirements;
- (2) the proposed site be located in proximity to skilled research and technical staff with expertise in operations conducted at biological and agricultural research facilities, and be in proximity to training programs for such expertise;

- (3) title to a site of at least 30 acres would be deeded at no or minimal cost to the U.S .Government, and that all NBAF construction (BSL-3 and BSL-4 laboratories) could occur at the 30-acre site;
- (4) in-kind contributions (e.g., deeded land, new utilities, roads, chilled and steamed water) would be donated by proposing consortia;
- (5) proposing consortia would support the National Environmental Policy Act (NEPA) effort; and
- (6) the proposing consortia could demonstrate that local and national agriculture stakeholder community members support, or at least do not oppose, locating the NBAF at the proposed site.

Upon receipt of this additional information from the consortia, a Federal team consisting of USDA and DHS employees conducted site visits to all the remaining sites. The intent of the site visits was to: (1) verify the information provided and representations made in the EOI submissions and additional information submitted; and (2) enable evaluation committee representatives to view any observable physical conditions and constraints at the proposed site and, if applicable, view the site's utilities and infrastructure. In addition, I separately visited each of the sites personally so I could reference first-hand knowledge when being briefed by the site-selection team.

Based on Federal employee evaluation team's analysis of the additional information and observations on the site visits, the evaluation team recommended to me which sites should advance for further evaluation. As the Selection Authority, I determined that **five sites** met the evaluation criteria and DHS preferences, and would therefore be advanced as reasonable alternatives to be studied in the Environmental Impact Statement (EIS).

Although not part of the competitive site selection process, Plum Island was determined to be a reasonable site to advance for study in the EIS, making a total of **six sites** for consideration. The basis for including Plum Island as a viable alternative was fourfold:

- (1) NEPA specifically requires the proposing Federal agency to evaluate the range of all "reasonable alternatives" to a proposed action, where reasonable alternatives are defined as those which are "practical or feasible from the technical and economic standpoint and using

common sense, rather than simply desirable from the standpoint of the applicant.”;

(2) Plum Island currently performs much of the existing research and houses the existing workforce assessing potential threats to animals from foreign animal diseases and zoonotic diseases;

(3) Plum Island currently fulfills a portion of the goals and mission identified for the NBAF and meets some of the NBAF criteria, including having a skilled workforce in a BSL-3 environment; and

(4) Plum Island could reasonably be internally evaluated throughout the EIS process, given that DHS already owns Plum Island and did not believe it appropriate to respond to “its own request-for-EOI [expression of interest].”

The Notice of Intent (NOI) to prepare an EIS, which was published in the Federal Register on July 31, 2007, listed the six site alternatives that will be studied in the Environmental Impact Statement (EIS) and began the NEPA process for the proposed NBAF. In accordance with NEPA, DHS is also considering as part of the EIS process a “no action alternative” (i.e., the NBAF would not be built).

DHS has established an evaluation process utilizing a team of Federal officials from DHS and USDA to review, for all six alternatives, the EIS analysis as well as other factors such as threat risk assessment, site cost analysis, site characterization, PIADC facility closure and transition cost, DHS’s evaluation criteria and preferences used to down-select the sites, and other programmatic considerations. This will allow the team to recommend the site alternative which is most beneficial to the Government and to the public. The Draft EIS is scheduled to be released for public comment in May 2008, followed by public meetings at each of the six site alternatives. The Final EIS will be published at the end of September 2008. Following completion of the final EIS, a Steering Committee consisting of Federal employees will make a final recommendation to me.

I expect to publish a Record of Decision (ROD) in the fall of 2008. The ROD will notify the public of the decision on the proposed action of whether to build the NBAF and, if so, where to build and operate it. The ROD will also document the reasons for the decision. If the decision is made to build the NBAF, site-specific NBAF design efforts will follow, and NBAF construction would be planned for 2010, and the facility would be commissioned by the end of 2014.

I want to emphasize that no decisions will be made on the final site selection until the appropriate environmental and safety risk assessments have been completed. Those are presently underway as part of the Environmental Impact Statement process. If the NBAF is built, and no matter where it is sited, the utmost in biosafety and biosecurity will be utilized to make this a safe and secure facility.

In the intervening decades since the PIADC was built, significant advancements have been made in laboratory design and bio-containment measures and protocols. While there is always a risk of human error—the recent suspected release of live foot-and-mouth disease virus from the Pirbright Campus in England remains an isolated case in point—the redundancies built into modern research laboratory designs and the latest biosecurity and containment systems, coupled with continued training and monitoring of employees, effectively minimizes these risks. Consequently, I have every reason to believe that the assessments will show that, from a biosecurity and public safety perspective, siting the NBAF on the U.S. mainland is a viable alternative.

Regardless of which site is chosen, implementation would necessitate decommissioning the current Plum Island facility, and those costs plus the costs to transition to the new facility, regardless of location, would be considered in the final decision making analysis.

The estimated facility cost for this project is \$451M, not including the cost for site infrastructure, IT, security, or utilities. The final facility cost is being determined as part of the decision process. To date, \$46M has been appropriated for the NBAF to do planning, siting studies, and the Environmental Impact Statement.

Research involving the use of live FMD virus may occur on the U.S. mainland, subject to the Secretary of Agriculture making a determination that such study on the mainland is necessary and in the public interest and issuing a permit for such research to be conducted on the mainland. Prior assessments have determined that since the 1950s, when Plum Island was built, the subsequent evolution of bio-containment technology allows safe research and diagnostics of foreign animal diseases to take place on the U.S. mainland.

Conclusion

In summary, the planned NBAF would 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 growing. Plum Island has done and continues to do an excellent job in the defense of the Nation against foreign animal disease threats, but the age of its facilities and its limited capacity restricts research and diagnostic studies and is slowing the development of needed countermeasures. Further, there are no facilities in the Nation to fully handle large animals and address zoonotic diseases that affect both large animals and humans. NBAF is needed to attract and retain the scientists, technicians, researchers, and veterinarians needed to defend against current and future threats for the next 50 years and to fulfill the mandate of HSPD-9. Therefore, DHS is committed to creating the next-generation capability and supporting our USDA partners by making the planned NBAF a reality.