

December 14, 2007

The Honorable John D. Dingell Chairman, Committee on Energy and Commerce United States House of Representatives Washington, D.C. 20515-6115

The Honorable Bart Stupak
Chairman, Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
United States House of Representatives
Washington, D.C. 20515-6115

Dear Chairmen Dingell and Stupak:

I write to follow up on the United States Department of Agriculture's ("USDA") October 1, 2007 response to the September 20, 2007 letter from the Committee and Subcommittee (collectively the "Committee"), regarding the "management, operation, and activities of the Department of Homeland Security's ("DHS's") Plum Island Animal Disease Center ("PIADC")" and the "recent proposal by DHS to close the PIADC and relocate its operations to a new facility, to be called the National Bio and Agro-Defense Facility ("NBAF")."

In our October 1, 2007 response to the Committee we requested the opportunity to meet with Committee staff to help us better understand how best to focus our document searches on the information the Committee considers most important. As neither of the individuals identified as points of contact in our initial letter were contacted, the Agricultural Research Service ("ARS"), the Animal and Plant Health Inspection Service ("APHIS") and relevant Departmental officials commenced a broad search of their records.

USDA is committed to assisting the Committee in this request for information in a manner that accommodates both the Committee's legitimate oversight interests and the interests of the Executive Branch. We had hoped to provide a response sooner, however, the Committee's seventeen separate inquiries have required a substantial amount of work on the part of the Department. Due to the extremely broad scope of the request, we devoted a substantial amount of personnel time, effort, and resources to this undertaking.

We are providing the Committee with 647 pages of responsive materials (Bates stamped USDA-PIADC-000001 thru USDA-PIADC-000647), which are enclosed herein. We are also providing a "Questions and Answers" document prepared by ARS and APHIS that responds to each of the seventeen inquires individually. USDA has coordinated its Questions and Answers with DHS.

Included in today's production are documents of a deliberative nature that would normally not be shared outside the Executive Branch. We are nonetheless providing them in an effort to accommodate the Committee. Please be advised that we have identified two additional documents that are of a distinct and sensitive character due to their highly deliberative nature reflecting internal decision-making processes involving the Office of the Secretary. These two documents have not been included in the attached production. If the Committee wishes to discuss this matter, we would be willing to explore the possibility of further accommodation.

Should we find additional documents that are responsive to the Committee's September 20, 2007 request, we will provide them as soon as possible. Thank you very much for your consideration. If members of your staff would like to discuss this matter further, please ask them to contact L. Benjamin Young, Jr., Assistant General Counsel, at 202-720-5565.

Sincerely,

Marc. L. Kesselman General Counsel

Enclosures

cc: The Honorable Joe Barton

Ranking Member, Committee on Energy and Commerce

The Honorable Ed Whitfield Ranking Member, Subcommittee on Oversight and Investigations Committee on Energy and Commerce

The Honorable Jay M. Cohen Under Secretary for Science and Technology United States Department of Homeland Security

The Honorable Gale Buchanan Under Secretary for Research, Education and Economics United States Department of Agriculture

The Honorable Bruce Knight
Under Secretary for Marketing and Regulatory Programs
United States Department of Agriculture

United States Department of Agriculture Questions and Answers Response to the U.S. House of Representatives, Committee on Energy and Commerce September 20, 2007 Request for Information: Plum Island Animal Disease Center

1. Does USDA agree with the DHS proposal to close the Plum Island PIADC and transfer its operations elsewhere?

USDA supports DHS in their effort to replace the PIADC facility with a state of the art facility with Bio Safety Level-Three ("BSL-3") and Bio Safety Level-Four ("BSL-4") capability.

2. Please provide copies of all records, including memoranda, reports, studies, etc. dated January 1, 2002 or later, whether draft or final, discussing whether Plum Island should be closed and/or relocated.

The Agricultural Research Service ("ARS") paid for two studies under one contract with Science Applications International Corporation ("SAIC"), which used an expert panel to investigate the question of moving the research program to the mainland. These 2002 studies was provided to the DHS Under Secretary for Science and Technology as part of the transfer of Plum Island to DHS in 2003. These SAIC studies are included in the attached package of documents.

3. Has an assessment been conducted that reviewed the need for the closure, expansion, or replacement of the PIADC? If so, please provide a copy.

USDA initiated a study in 1999 to assess the renovation or replacement of the existing facilities at PIADC, including the addition of BSL-4 space. This study was completed by the Architect and Engineering firm Kling-Lindquist in May 2001. A copy of the study is included in the attached package of documents. The 2002 studies performed by SAIC, provided in response to request #2 above, are also responsive to this request.

4. Plum Island covers some 840 acres of land. If there is a need to expand the PIADC facilities at Plum Island, is there enough room at PI to accommodate that expansion?

DHS has responsibility for making the site selection decision for the proposed NBAF. DHS has determined that Plum Island has sufficient acreage to accommodate the proposed NBAF, and has included Plum Island as a site alternative for the proposed NBAF in the Environmental Impact Statement it is preparing.

5. Please provide a detailed description of USDA's role in the planning, construction, and operation of the proposed NBAF.

Representatives from ARS and the Animal and Plant Health Inspection Service ("APHIS") have met with DHS and the NBAF Design Partnership on six occasions since January 2007 to establish design criteria for the facility to meet the program needs and stay within the anticipated budget of \$451,000,000.00. APHIS and ARS provided detailed program requirements documents that outlined the current programs conducted at PIADC as well as the expected growth for the NBAF facility. USDA has also provided representatives to serve on the DHS site

selection committee and the site inspection team. The future operations of the proposed facility have not yet been discussed in detail.

While the future operations of the proposed NBAF facility may be different than the operations at PIADC, the current operations could provide a model for future NBAF operations. Currently, the Department of Homeland Security (DHS) and the United States Department of Agriculture (USDA) administer the Plum Island Animal Disease Center (PIADC) through a Board of Directors ("the Board") and the PIADC Senior Leadership Group ("SLG"). The Board consists of the Director of the Office of Research and Development, Science and Technology Directorate, DHS; and the Administrators of ARS and APHIS. The Chair is the Director, S&T, DHS. The Board is responsible for coordination and oversight of all matters among agencies relating to the management, administration, research and operations at PIADC.

The members of the SLG consist of Center Director, PIADC, DHS (Chair); Chief, FADDL, APHIS, USDA; Research Leader, ARS, USDA; Deputy Director of Science, DHS; and the Deputy Director of Operations, DHS (Executive Secretary). The SLG is responsible for establishing operational (including security) procedures and practices for PIADC and conducting strategic planning for future needs. The SLG also provides oversight to ensure that PIADC operational procedures and practices are followed by all users of PIADC. Each agency provides a leader to manage its own programs at PIADC.

6. The scientific research conducted at the Plum Island PIADC typically requires highly trained professionals. Please provide a list of researchers employed at the PIADC, with names omitted, showing the education level, field of expertise and pay grade/compensation rate for each.

Table 1: ARS Personnel

GRADE	EDUCATION	Field of Expertise
6	HS	Procurement
7	BA	Administration Accounting/Human Resources
7	BA	Administration Accounting/Human Resources
7	BS	Pathology
9	BS	Microbiology
9	BS	Molecular Biology
9	MS	Cellular Biology
9	BS	Molecular Biology
11	MS	Molecular Biology
11	BS	Microbiology
11	BS	Virology
11	BS	Virology
11	MS	Microbiology
11	PhD	Molecular Biology
11	MS	Immunology
11	PhD	Microbiology
11	PhD	Molecular Biology
12	PhD	Microbiology

12	DVM, PhD	Immunology
12	DVM, PhD	Pathology
12	Associate	Budget & Administrative Management
12	PhD	Microbiology
13	DACVP	Pathology
14	DVM, PhD	Virology
14	PhD	Virology
14	PhD	Immunology
14	PhD	Computational Biology
15	DVM, PhD	Virology
15	PhD	Virology
ORISE*	DVM	Microbiology
ORISE	MS	Virology
ORISE	DVM, PhD	Immunology
ORISE	DVM, PhD	Pathology/Virology
ORISE	MS, DVM	Virology
ORISE	BS	Virology
USDA Collaborator	HS	Microbiology
Visiting	PhD	Molecular Biology
Visiting	PhD	Virology
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* ORISE = Oak Ridge Institute for Science and Education, a Department of Energy Institute
These are post-doctoral fellows hired by ARS through ORISE, who are physically located and perform work at PAIDC.

Table 2: APHIS Personnel

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EDUCATION	Field of Expertise/Title			
Vacant	Office Automation Assistant			
BS	Laboratory Technician			
BS	Laboratory Technician			
AA	Veterinary Diagnostic Program Assistant			
BS	Training Technician			
BS	Vaccine Bank Microbiologist			
BS	Laboratory Technician			
BS	Laboratory Technician			
MS	Laboratory Technician			
BA	Laboratory Technician			
MS	Laboratory Technician			
DVM, PhD	Laboratory Technician			
MS	Laboratory Technician			
BS	Laboratory Technician			
Vacant	Calibration Quality Technician			
AA	Laboratory Control Technician			
Vacant	Microbiologist			
AA	IT Specialist			
BS	Professional Development Staff Trainer			
	Vacant BS BS BS AA BS BS BS BS BS MS BS MS BA MS DVM, PhD MS BS Vacant AA Vacant AA			

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11	PhD	Microbiologist
11	MS	Microbiologist
11	BS	Microbiologist
11	BS	Microbiologist
11	BS	Microbiologist
11	PhD	Microbiologist
12	BS	Quality Assurance Program Analyst/Chemist
12	DVM, PhD	Veterinary Medical Officer
12	MS	Microbiologist
12	PhD	Microbiologist
12	Vacant	Microbiologist
12	PhD	Microbiologist
12	DVM, PhD	Microbiologist
12	MS	Microbiologist
12	PhD	Microbiologist
13	DVM, PhD	Veterinary Medical Officer
13	DVM, PhD	Veterinary Medical Officer
13	PhD	Microbiologist
13	PhD	Microbiologist
13	DVM, PhD	Pathologist
14	DVM, MPH	Senior Staff Veterinarian
14	DVM, PhD	Proficiency and Validation Services Section Head
14	DVM, PhD	Diagnostic Services Section Head
14	DVM, PhD	Reagents and Vaccines Services Section Head
15	DVM, PhD	Foreign Animal Disease Diagnostic Laboratory Director

7. Closing the PIADC and transferring its functions to the new NBAF would require the transfer of the current research staff to the new location. Experience at other government laboratories shows that a large number of such personnel would be unable or unwilling to relocate, thus causing a substantial loss in expertise and continuity of operations. Has USDA estimated the number of researchers who would be likely to refuse a transfer from Plum Island? Please provide copies of any such analysis.

USDA has not made any estimate of employees willing or not willing to relocate to a new NBAF location other than Plum Island. This will be difficult to assess until the final NBAF site and timing of the relocation are determined. In addition, the move will not occur for at least six to seven years, during which time there could be significant personnel turnover. Consequently, any evaluation done at this point would not be reflective of the future staff's willingness to relocate.

8. Please provide copies of all records pertaining to the need for and cost of environmental cleanup at PIADC.

USDA currently has no responsive documents. Any records USDA may have previously had pertaining to the need for and cost of environmental clean up at Plum Island Animal Disease Center would have been transferred to DHS in 2003.

9. How many people are employed by USDA at PIADC?

Currently there are 69 USDA employees at PIADC, 29 ARS and 40 APHIS. APHIS also currently has four vacancies at PIADC. Additionally, there are nine staff members classified as visiting scientists or collaborators working with ARS on site.

10. Have any outside contractors been involved in proposing, analyzing, or planning the closing of the Plum Island PIADC or the establishment of the NBAF? If so, please provide their names and roles.

The 2002 studies performed by SAIC, provided in response to request #2 above, were contracted for by USDA prior to the transfer of PIADC to DHS. Subsequent to the 2003 transfer of PIADC to DHS, USDA has not contracted for any studies or other work in relation to DHS' current proposal to close PIADC and relocate its research activities to a new NBAF.

11. Please provide a description of all renovations and new construction carried out at Plum Island in the past 10 years. Please provide detailed cost data by year for each of the past 10 years on the cost of such renovations and new construction.

A list of renovations to the PIADC facilities is included in the attached package of documents. This list includes the date of the improvements made, the cost of the improvements made, and a description of the improvements made to Plum Island facilities by USDA in the last ten years. The last improvements made by USDA at Plum Island were completed in 2002, prior to the facilities being turned over to DHS in 2003. USDA has not constructed any new facilities at PIADC in the last ten years.

12. Classical swine fever and African swine fever could be devastating to the swine populations of the United States. Yet, apparently, swine fever research at Plum Island has been severely curtailed in recent years. Why has swine fever research at PIADC been virtually eliminated? Please provide copies of all records since January 1, 1997, regarding the decision to reduce swine fever research at Plum Island.

The Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock, published by the Office of Science and Technology Policy ("OSTP") in 2003 names foot and mouth disease, and secondarily classical swine fever, as the foreign animal diseases of greatest significance. The OSTP report was based upon the Strategic Research Document: Strategic Research Targets to Protect American Livestock and Poultry from Biological Threat Agents: Report from the WMD Counter Measures Working Group – Animal Pathogen Research and Development Subgroup, of October 31, 2003. ARS focuses its limited resources on these highest priority diseases. Foot and mouth disease has the potential to have disastrous impacts on the swine and other livestock industries, and new solutions must be found to reduce or prevent its impact. A copy of the 2003 OSTP report is included in the attached package of documents.

ARS' research program funding was reduced in half in the FY 2004 appropriations law, and ARS had to eliminate one of two management units, resulting in the loss of the African Swine Fever Research Program and half of the Classical Swine Fever Research Program. A December

- 1, 2004 internal USDA budget document discussing these cuts is included in the attached package of documents. The projects that were cut included research on:
 - high consequence pathogen detection;
 - functional pathogen genomics: virulence and host range genes of swine fever virus;
 - identification and characterization of African swine fever virus protective antigens;
 - detection and diagnosis of hog cholera;
 - advanced animal vaccines and diagnostic applications;
 - advanced veterinary vaccines and diagnostics;
 - program for prevention of animal infections and advanced technologies for vaccines and diagnostics; and
 - development of rapid real time PCR-based assays for selected OIE class A diseases.
- 13. Has USDA been contacted by members of the agricultural and livestock industries regarding the proposal to close Plum Island and transfer FMD and other livestock disease research to another facility in the United States? If so, please provide copies of all records pertaining to such contacts.

The current DHS proposal to close PIADC and relocate its research activities to a new NBAF was published on the Federal Business Opportunities website on January 17, 2006 and in the Federal Register on January 19, 2006. DHS personnel were listed as the official points of contact in both of these public notifications. Accordingly, USDA has not kept an official log of contacts received, nor has USDA received many contacts as outside organizations have been directed through the Federal Register and Federal Business Opportunities notices to contact DHS. We have searched our records for evidence of any contacts, and were able to find the following documents, copies of which are included in the attached package of documents.

• Letter from Dr. Edward Knipling, Administrator, Agricultural Research Service, and W. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service, to Animal Production and Health Organizations (list follows), Re: DHS Proposal to Close and Relocated PIADC, Fact Sheet from DHS website attached (Aug. 22, 2005)

List of Recipient Entities

- Animal Agriculture Coalition
- National Cattlemen's Beef Association
- National Pork Producers Council
- National Pork Board
- National Chicken Council
- United Egg Producers
- National Turkey Federation
- American Sheep Industry Association
- American Horse Council
- American Farm Bureau Federation
- National Meat Association
- American Association of Veterinary Laboratory Diagnosticians
- American Veterinary Medical Association
- United States Animal Health Association
- National Assembly of Chief Livestock Health Officials

- National Institutes of Animal Agriculture
- National Association of State Departments of Agriculture
- Communications Officers of State Departments of Agriculture
- Animal Agriculture Communicators Group
- Letter from the United States Animal Health Association, to Secretary Johanns, Re: Transmission of Resolutions No. 10 "Federal Funding for the National Animal Health Laboratory Network" and No. 40 "Funding for Bovis Research on Vaccines and Antivirals for Foot and Mouth Disease and Classical Swine Fever" (Dec. 14, 2005)
- Letter from W. Ron DeHaven, Administrator, Animal and Plant Health Inspection Service, to Glenn Slack, President and Chief Executive Officer, National Institute for Animal Agriculture, Re: USDA response to National Institute for Animal Agriculture 2005-2006 Resolution Number 45 "Funding for Plum Island Facilities" (Feb. 22, 2006)
 - This letter was in response to a November 28, 2005 incoming letter transmitting the resolutions. We have been unable to locate a copy of the incoming correspondence.
- Letter from the United States Animal Health Association, to Secretary Johanns, Re: Transmission of Resolution 32 "Stakeholder Involvement in the Development of the National Bio and Agro-Defense Facility" approved at the 110th Annual Meeting (Nov. 15, 2006)
- 14. Under Federal law (7 USC 113a), no live virus of foot and mouth disease may be introduced for any purpose into any part of the mainland USA without express permission of the Secretary of Agriculture, who must find that it is both necessary and in the public interest. Has the Secretary granted such permission at any time in the last 10 years? If so, please provide a list of all such instances.

No such permission has been granted in the last 10 years.

15. Do you intend to grant permission for the transfer of live foot and mouth disease from the PIADC to a new location on the mainland USA, if the PIADC is closed?

The Administration has proposed legislation that would provide specific authorization for USDA to establish research facilities and conduct research and diagnostics for highly infectious disease agents, such as foot and mouth disease, on the U.S. mainland. Should the proposed specific authority not be enacted, USDA will consider granting permission for the transfer of live foot and mouth disease from PIADC to an appropriate facility on the U.S. mainland based on relevant information available at the time. Such consideration would be based on factors that are currently unknown, including the final location of the NBAF. Accordingly, it is premature to speculate at this time as to whether permission to transfer live foot and mouth disease to the new NBAF would be granted.

16. The PIADC includes a BSL-3 laboratory. Please identify the types of research currently being performed in the BSL-3 laboratory and which have been performed at any time since January 1, 1997.

USDA can provide answers only for research programs run by ARS and APHIS at PIADC. All of ARS and APHIS' work is carried out under strict operating procedures with multiple layers of safeguards: physical, mechanical, and procedural.

Currently, ARS' work includes active research programs working with foot and mouth disease virus, classical swine fever virus, and vesicular stomatitis. ARS' work includes basic research and early development of vaccines, biotherapeutics, and diagnostics, while DHS carries out advanced development and validation of vaccines and biotherapeutics. In the period since January 1, 1997, ARS has also conducted African swine fever and classical swine fever research at PIADC; this research was eliminated due to funding cuts in FY 2004, as explained in response to request #12 above.

The APHIS mission at Plum Island focuses on diagnostics for suspected foreign animal diseases, such as foot and mouth disease, classical swine fever, and African swine fever. The Foreign Animal Disease Diagnostic Laboratory ("FADDL") at Plum Island currently has the capability of diagnosing over 30 foreign animal diseases. Each year, over 600 investigations are conducted at FADDL, and FADDL currently acts as the National Reference laboratory for them. FADDL actively supports the National Animal Health Laboratory Network, and also provides foreign animal disease diagnostic training schools every year to educate on the recognition and diagnosis of diseases.

17. It is our understanding that DHS plans to construct a BSL-4 laboratory as part of the new NBAF. In your opinion, is a BSL-4 laboratory needed at either Plum Island or at the proposed NBAF to conduct research on plant and animal disease? Please provide copies of any analysis that has been performed on the issue.

DHS has prepared several gap assessments which have identified the lack of adequate facilities that would allow research and development of countermeasures for livestock against zoonotic diseases (diseases transmissible from animals to humans). The current research scientific program only focuses on three diseases – foot and mouth disease, vesicular stomatitis, and classical swine fever. Several other foreign animal diseases are known to pose a threat to U.S. agriculture. The current facilities available in the U.S. are not adequate to study and develop countermeasures against zoonotic and vector-borne diseases such as Rift Valley Fever, Hendra, and Nipah viruses in the relevant large animal hosts; animal research for these viruses requires a BSL-4 facility. In order to protect U.S. agriculture and human health, it is critical that the USDA foreign animal disease diagnostic program have the capability of diagnosing and working with these agents as well as any new highly infectious pathogen that may emerge. With population growth, environmental changes, and the rapid movement of people, goods, and materials across the globe, vector-borne diseases pose some of the most significant threats to our country as recently demonstrated with the West Nile virus.

In addition to the DHS gap assessments and in accordance with the Fiscal Year 2002 Defense Appropriations Act, the Department of the Army and USDA jointly prepared a report to study the feasibility of a shared research facility. This report was finalized in March of 2005. While the primary focus of the report was the creation of additional biocontainment facilities, not the replacement of Plum Island, the report does contain references to Plum Island and to the lack of BSL-4 facilities in the United States. A copy of the March 2005 report is included in the attached package of documents.