



United States
Department of
Agriculture

Office of the
General
Counsel

Washington,
D.C.
20250-1400

December 18, 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 supplement the United States Department of Agriculture's ("USDA") December 14, 2007 and October 1, 2007 responses 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")."

As stated in our prior letters, and as demonstrated by the accommodations that we have made to date, USDA is fully committed to assisting the Committee in its request for information in a manner that accommodates both the Committee's legitimate oversight interests and the interests of the Executive Branch.

Assistant Secretary Strachan and I very much appreciate that your staff was willing to meet with us this morning to discuss issues of mutual concern. As explained, USDA is very concerned about maintaining the effectiveness of our deliberative processes. As I am sure you would agree, the Department can function best only if the Secretary is able to receive the candid advice of his senior advisors. When there is no expectation that such deliberations will remain confidential, candor suffers, the quality of decision making is diminished, and the public is ultimately harmed.

As stated in the December 14 letter, we had located two responsive documents that were not included in the initial production. Each of these is a pre-decisional document of a highly sensitive and deliberative nature that would normally not be shared outside the Executive Branch. We are nonetheless providing one of these documents herewith in an effort to accommodate the Committee (Bates stamped USDA-PIADC-000648 thru USDA-PIADC-000652). We appreciate the Committee's recognition that the second document – talking points

from the Assistant Secretary for Congressional Relations and the Deputy Chief of Staff to the Secretary in advance of a meeting with Members of Congress – is unnecessary to the Committee's investigation.

The attached document being provided today is an Informational Memorandum to the Secretary of Agriculture from the Under Secretary for Research, Education, and Economics, and from the Under Secretary for Marketing and Regulatory Programs dated April 28, 2005. Although the Department has a very strong interest in preserving the confidentiality of its internal deliberations, we are willing to make this accommodation because much of the contents are informational about decisions that ultimately do not rest with the Secretary of Agriculture. Additionally, we understand that this document lies at the core of the Committee's inquiry, and that this memorandum is the only means by which the Committee can obtain the information it seeks. We also took into consideration the length of time that the inquiry has been pending at the Department. Thus, our decision to produce this document is based upon a careful weighing of these and other factors that are highly dependent upon the circumstances presented here.

Further regarding the document provided today, we are concerned that disclosure of USDA's internal deliberative documents outside Congress would have a potential chilling effect on the candor and quality of future Executive Branch deliberations regarding matters of public health, and would hamper our ability to assert applicable exemptions and privileges under the Freedom of Information Act and other disclosure statutes. Therefore, we request that these documents be used for Committee purposes only and that their confidentiality be strictly maintained. Accordingly, should the Committee determine that public disclosure is necessary in the exercise of its responsibilities; we request an opportunity to discuss our concerns with the Committee before the documents are released.

As I indicated to your staff this morning, I will follow up on two of the questions that we answered in our December 14 response, but barring the discovery of such additional information, we will consider our response to the September 20, 2007 inquiry complete – with the understanding that the Committee may follow up with additional questions in writing. 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

Research
Education
Economics

Office
of the Under
Secretary

Room 216W
Jamie L. Whitten Building
Washington, DC 20250-0110

SISOJK
1/10/05

INFORMATIONAL MEMORANDUM FOR THE SECRETARY

THROUGH: Dale Moore
Chief of Staff

FROM: Joseph J. Jen
Under Secretary

APR 27 2005

William T. Hawks
Under Secretary
Marketing and Regulatory Programs

APR 28 2005

SUBJECT: Replacement of the Plum Island Animal Disease Center (PIADC)

ISSUE:

The Department of Homeland Security (DHS) proposes to plan and construct a new facility probably on the mainland. There are important issues that require Department of Agriculture (USDA) attention and involvement.

DISCUSSION:

USDA has had a presence on Plum Island for 50 years for research and diagnostics on foreign animal diseases that pose risks to the U.S. livestock industry. By U.S. statute, foot-and-mouth disease (FMD) research with the live virus can only be conducted at an offshore location. Additionally, only the Secretary of Agriculture can authorize bringing the FMD virus onto the mainland under two special circumstances--when "...necessary and in the public interest to conduct research..." or "in the event of an outbreak of FMD..."

The real property assets and liabilities of PIADC and the responsibility for its operations were transferred from USDA to DHS in June 2003 in accordance with the Homeland Security Act of 2002. DHS is obligated to accommodate the continued presence of USDA program functions, research - Agricultural Research Service (ARS), and diagnostics - Animal and Plant Health Inspection Service (APHIS), in the PIADC facilities. Collectively, ARS and APHIS maintain at the Center a technical staff of about 50 personnel supported by an annual appropriation of about \$8 million. This work is essential in order for USDA to meet its program responsibilities to help protect the U.S. food and agriculture system.

INFORMATIONAL MEMORANDUM FOR THE SECRETARY
PAGE 2

PIADC facilities are very old, outdated, very expensive to operate, in extensive need of repair and modernization, and do not meet the highest level of biocontainment security, biosafety level 4 (BSL-4), and other program requirements of DHS. USDA acknowledges these facilities shortcomings and limitations. Several years ago, USDA developed tentative plans for a \$225 million onsite modernization program, but these plans were preempted upon the transfer of the facility custodianship to DHS.

Biocontainment facilities to meet USDA and DHS needs would be both biosafety level 3 (BSL-3) and BSL-4. A BSL-3 facility as currently on Plum Island protects against environmental release of organisms such as FMD. A BSL-4 facility would protect against environmental release and provide personal protection to personnel against agents that infect both animals and man for which there is no protection such as a vaccine or anti-viral. The Nipah virus which killed both pigs and people in Malaysia is an example.

In response to social and political considerations, DHS has made a policy decision to not construct or operate a BSL-4 facility on Plum Island. Accordingly, DHS proposes to plan and construct a totally new and modern foreign animal disease facility which may be on the mainland at a location yet to be determined. The facility might even be BSL-3 and BSL-4 structures at different locations. The new facility will be designed to meet the program requirements of both DHS and USDA. The new facility will fulfill the requirement for biocontainment facilities identified in Homeland Security Presidential Directive-9 and is currently designated as the National Bio and Agrodefense Facility (NBAF). Once the new replacement facility is available, the existing facilities on Plum Island no longer will be occupied by DHS or USDA.

The President's budget for fiscal year (FY) 2006 includes for DHS a \$23 million request to plan and design the new facility. DHS estimates a total of \$451 million will be required by FY 2008 for construction. DHS expects to receive the requested FY 2006 design funds and, under that premise, is proceeding now with available FY 2005 funds to let a \$3 million contract in May 2005 for a conceptual design of the new facility and to evaluate location options. DHS has requested ARS' and APHIS' assistance to define facility program requirements, identify suitable location options, and develop and implement a communication plan for customers and stakeholders.

DHS desires to deal with these matters promptly in the remainder of FY 2005 so that formal facility planning and design can begin in FY 2006. This latter process will require up to 2 years followed by a 3- to 5-year construction period, assuming full construction funding is available. In the meantime, existing USDA and DHS programs at PIADC will continue there.

There are numerous issues for USDA to consider:

1. What is the USDA policy position on the DHS proposal to plan for a new facility on the mainland and what is the USDA role?

INFORMATIONAL MEMORANDUM FOR THE SECRETARY

PAGE 3

Comment: By virtue that the DHS proposal is embodied in the President's FY 2006 budget request and that HSPD-9 delegates responsibility to DHS and USDA to plan for an adequate National Bio and Agrodefense capacity, USDA should publicly support the DHS concept and proactively assist in the planning.

2. Will the Secretary authorize FMD live virus research and other work to be carried out on the mainland?

Comment: Short of new legislation to repeal the limit on FMD work to an offshore location, the Secretary will have to exercise his delegated authority to allow FMD work to be conducted on the mainland in the new facility as being in the public interest.

3. Can FMD and other exotic animal disease work be carried out safely in biocontainment facilities on the mainland and not pose risk to the U.S. livestock industry?

Comment: A study commissioned by USDA in 2002 concluded that the FMD virus and other exotic animal pathogens of concern to USDA could be fully contained and safely handled within a BSL3-Ag facility, as is being done in other countries, including Canada, the United Kingdom, Switzerland, Spain, Germany, and Brazil. Thus, USDA judges that these pathogens would not pose a risk to the external environment and the livestock industry. A second study indicated that a BSL-4 facility for large animal work also could be safely located on the mainland. However, these issues will continue to be controversial among some parties (see further discussion below).

4. What is the agricultural need for a BSL-4 animal health biocontainment facility?

Comment: BSL-4 biocontainment facilities are designed and required to protect humans working with highly contagious exotic agents that can infect both humans and animals (zoonotic diseases) for which there is not adequate human protection (vaccines). DHS has stated its needs for a BSL-4 capability. The USDA needs are less definitive because there are relatively few known BSL-4 agents that pose a severe risk to the U.S. livestock industry. However, there is always the potential for new disease agents, either naturally occurring or intentionally bioengineered, that could cause harm to both humans and livestock species. Having the capability and readiness to work with such new and unknown agents under the highest level of biosecurity, when and if needed, would be an important asset for fulfilling USDA responsibilities for agrodefense.

5. What are the anticipated reactions by the U.S. livestock industry and associated stakeholders to the DHS plan and USDA policy position?

Comment: In the past, the food animal industries have strongly opposed having the FMD virus on the mainland, even in biocontainment, because of the perceived risk to the livestock population due to an accidental escape. This opposition can be expected to continue and be

INFORMATIONAL MEMORANDUM FOR THE SECRETARY
PAGE 4

intense. USDA will have to work carefully with these customer and stakeholder organizations to help inform them of the adequacy of the DHS plan and USDA support. Ultimately, the stakeholders can be expected to exert their influence one way or the other through the congressional appropriation process and other forms of legislation.

6. What are the potential cost ramifications for USDA?

Comment: DHS has implied to this point that it will seek the necessary construction funds through their own budgetary process. However, because of the large sum of total funding required, and if delays or other difficulties are encountered in the appropriation process, there is the possibility that DHS at some point might seek USDA funding assistance, especially since USDA will occupy a significant portion of the new facility. The existing statutory language requiring DHS to provide facility and operational support for USDA programs at PIADC, at no cost to USDA, may no longer be applicable to a new mainland facility.

In addition to the \$451 million construction cost for the new facility, DHS also estimates up to \$100 million will be required to equip the new facility, relocate existing personnel and programs, and prepare the old PIADC facility for disposition. USDA can be expected to be called upon by DHS to finance its share of the relocation and new equipment costs, as well as increased ongoing operational support. USDA should seek clarification of these funding matters with DHS early in the planning process.

7. What are the USDA views on the location options for the new facility?

Comment: DHS has not predetermined or expressed a commitment to a particular site location but desires to engage USDA and stakeholders in an open process to identify and evaluate options in accordance with certain criteria. We can expect, however, that Fort Detrick in Frederick, Maryland, will emerge as one prominent option because a Biodefense Campus of relevant Federal programs already exists there, including the Department of Defense, Department of Health and Human Services, DHS, and USDA. The USDA presence is the ARS foreign plant disease biocontainment research program. The facility housing this ARS program is also in need of modernization which is being supported by an FY 2006 budget request of \$3 million for planning and design. USDA should also support Ft. Detrick as a high potential option for the site of the PIADC replacement.

It is plausible to expect that Ames, Iowa, will also be suggested as a location option in light of USDA's strong presence there and our ongoing \$462.3 million modernization program for the National Centers for Animal Health. USDA should not support the Ames option because the new facility capacity there is already fully committed to domestic animal disease programs and it would be important to keep the exotic pathogen work at a completely separate location for biosecurity purposes.

INFORMATIONAL MEMORANDUM FOR THE SECRETARY
PAGE 5

Although general stakeholder resistance is anticipated for all potential location options on the mainland, we can expect a more intense and focused opposition at any particular location by local public and stakeholder interests. This would be an expression of the "not in my backyard" syndrome.

An exception to this principle might occur for some State and University co-location options where local interests might welcome the prospect of a new \$451 million Federal facility.

The DHS Directorate for Science and Technology has offered to meet with the Secretary and other senior USDA officials to further brief them on the DHS plans for a new NBAF to accommodate existing PIADC programs and expanded homeland security activities.

SUMMARY:

DHS is launching an aggressive initiative to plan and construct a new NBAF, probably on the mainland, to replace PIADC and to sustain essential biosecurity work on exotic animal diseases that also potentially pose public health risks. The new facility will accommodate relevant USDA programs, but there will be increased cost ramifications for USDA. The plan can be expected to be controversial among the public and industry stakeholders with respect to safety, location, and the need for a BSL-4 capability. USDA will become very involved and will have to play a strong role in helping to shape the facility plan and location as well as in defending and communicating the need to the U.S. livestock industry and other USDA stakeholders.

The Secretary will be briefed on this issue at 2:00 pm on May 2, 2005, by William T. Hawks, Under Secretary, MRP, Joseph J. Jen, Under Secretary, REE, W. Ron DeHaven, Administrator, APHIS, and Edward B. Knipping, Administrator, ARS.