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The National Bio- and Agro-Defense Facility: Issues for Congress

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Dana A. Shea
Specialist in Science and Technology Policy
Resources, Science, and Industry Division

Jim Monke
Specialist in Agricultural Policy
Resources, Science, and Industry Division

Frank Gottron
Specialist in Science and Technology Policy
Resources, Science, and Industry Division

Congressional Research Service

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The National Bio- and Agro-Defense Facility: Issues for Congress

Summary

The agricultural and food infrastructure of the United States is potentially susceptible to terrorist attack using biological pathogens. In addition to the effects of such an attack on the economy, some animal diseases could potentially be transmitted to humans. These diseases are known as zoonotic diseases. Scientific and medical research on plant and animal diseases may lead to the discovery and development of new diagnostics and countermeasures, reducing the risk and effects of a successful terrorist attack.

To safeguard the United States against animal disease, Congress has appropriated funds to the U.S. Department of Agriculture (USDA) to engage in research at the Plum Island Animal Disease Center (PIADC), off the coast of New York, on animal diseases not native to the United States. When creating the Department of Homeland Security (DHS) in 2003, Congress transferred PIADC from USDA to DHS. Both USDA and DHS, in cooperation with USDA, conduct foreign animal disease research at PIADC, but PIADC has been identified as outdated and too limited to continue as the primary facility for this research.

Homeland Security Presidential Directive 9 tasks the Secretaries of Agriculture and Homeland Security to develop a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories for research and development of diagnostic capabilities and medical countermeasures for foreign animal and zoonotic diseases. To partially meet these obligations, DHS has requested Congress to appropriate funds to construct a new facility, the National Bio- and Agro-Defense Facility (NBAF). This facility would house high-containment laboratories able to handle the pathogens currently under investigation at PIADC, as well as other pathogens of interest. Six candidate sites have been identified, one of which is Plum Island. The DHS plans to select the site in 2008 and open NBAF in 2015. The final construction cost will depend on the site location and has been estimated to range between $648 million and $939 million, significantly exceeding 2005 baseline projections. Additional expenses, such as equipping the new facility, relocating existing personnel and programs, and preparing the PIADC facility for disposition, may exceed an additional $100 million.

The plans announced by DHS to establish the NBAF have raised several issues. Community concerns about safety and security, previously expressed about PIADC and other laboratories being built to study dangerous pathogens, are also being voiced about NBAF. Coordination between DHS and USDA, as well as prioritization and investment in agricultural biodefense, may be reassessed if more high-containment laboratory space becomes available.

Research with live foot and mouth disease (FMD) virus is allowed on the U.S. mainland only if explicitly permitted by the USDA Secretary. However, the Food, Conservation, and Energy Act of 2008 (P.L. 110-246) instructs USDA to issue such a permit to DHS for possession of FMD virus at NBAF, subject to select agent rules.

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The National Bio- and Agro-Defense Facility: Issues for Congress

Introduction

The agricultural and food infrastructure of the United States is a key component of economic productivity and growth. A terrorist attack on this infrastructure could damage the public trust in agricultural safety and quality and the nation's ability to provide food and other agricultural products.[1] Additionally, many animal diseases can infect humans.[2] These types of diseases are termed *zoonotic*. Scientific and medical understanding of such zoonotic diseases in their animal hosts may protect the animals themselves and could also lead to the discovery and development of new medical countermeasures for humans.

To safeguard the United States against the impacts of naturally occurring and intentional animal disease outbreaks, the U.S. Department of Agriculture (USDA) engages in animal disease research, including research into highly contagious animal pathogens and animal diseases not native to the United States.[3] Such research activities have historically been performed at the Plum Island Animal Disease Center (PIADC), located on Plum Island, an island near Long Island, New York.

When creating the Department of Homeland Security (DHS) in 2003, Congress transferred the operation of the PIADC facility from USDA to DHS, though USDA still maintains an active research program at PIADC. The DHS, in cooperation with USDA, has established its own research and development program at PIADC. As the federal government undertakes new efforts in human biodefense and defense against agroterrorism, DHS has characterized the PIADC facility as "reaching the end of its life cycle" and lacking critical capabilities and asserts it can no longer continue as the primary facility performing this research.[4]

Homeland Security Presidential Directive 9 (HSPD-9) tasks the Secretaries of Agriculture and Homeland Security to develop "a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop

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[1] For more background on the potential of terrorism directed against agriculture and food, see CRS Report RL32521, *Agroterrorism: Threats and Preparedness*, by Jim Monke.

[2] Examples include influenza, plague, West Nile virus, and Rift Valley fever.

[3] These diseases are sometimes referred to as foreign animal diseases (FAD).

[4] Department of Homeland Security, Science and Technology Directorate, *FY2006 Congressional Justification*, p. 44.

diagnostic capabilities for foreign animal and zoonotic diseases."[5] The Secretary of Homeland Security is to coordinate an acceleration and expansion of new and current countermeasure development. These countermeasures are to be against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases, including "countermeasure research and development of new methods for detection, prevention technologies, agent characterization, and dose response relationships for high-consequence agents in the food and the water supply."[6]

The Department of Homeland Security has announced that to meet the obligations of HSPD-9 it will establish a new facility, the National Bio- and Agro-Defense Facility (NBAF).[7] This facility would have high-containment laboratories able to hold the pathogens currently under investigation at PIADC as well as other pathogens of interest. The plans announced by DHS to establish NBAF have raised congressional and public concerns regarding its safety and security and policy questions about coordination between DHS and USDA regarding the research to be conducted at NBAF.

The DHS has narrowed the number of possible sites for NBAF to six. The sites are located in Athens, GA; Manhattan, KS; Madison County, MS; Granville County, NC; San Antonio, TX; and Plum Island, NY.[8] The DHS published a draft Environmental Impact Statement (EIS) on June 27, 2008, that addresses some of the effects building and operating the facility would have on each site.[9] The DHS expects to publish the final EIS in "late fall 2008"[10] and announce the selected site in December 2008.[11]

This report outlines current progress towards establishment of the NBAF, presents current and projected funding levels and timelines, and describes policy issues of potential interest to Congress, such as agency coordination, possession of viruses, construction timelines, disposition of PIADC, and community safety concerns.

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[5] Executive Office of the President, The White House, "Subject: Defense of United States Agriculture and Food," *Homeland Security Presidential Directive/HSPD-9*, January 30, 2004.

[6] Ibid.

[7] 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

[8] Ibid.

[9] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008. Available online at: [http://www.dhs.gov/xres/labs/gc_1187734676776.shtm].

[10] Ibid. p. ES-3.

[11] James Johnson, Office of National Laboratories, Science and Technology Directorate, Department of Homeland Security, Public statement at NBAF Draft Environmental Impact Statement Public Meeting, Washington, DC, July 24, 2008.

NBAF Research Goals

The DHS intends the new NBAF to be more than just a replacement facility for PIADC; DHS intends it to exceed both the capacity and capability existing at PIADC. The highest level of biocontainment available at PIADC is Biosafety Level 3 Agricultural (BSL-3Ag).[12] Because DHS plans to perform experiments with some pathogens that require a higher level of protection, approximately 10% of NBAF's gross square footage would be BSL-4 laboratories.[13]

The DHS foresees multiple uses and goals for the new facility:

- serving as a unique BSL-3 and BSL-4 livestock laboratory capable of developing countermeasures for foreign animal diseases;
- providing advanced test and evaluation capability for threat detection, vulnerability assessment, and countermeasure assessment for animal and zoonotic diseases; and
- supporting the countermeasure licensing process.[14]

The research agenda for NBAF is to be at least partially based on current risk assessments and subject to change as the risk assessments change. The DHS predicts that the facility will focus on foot and mouth disease (FMD), classical swine fever, African swine fever, Rift Valley fever, Nipah virus, Hendra virus, contagious bovine pleuropneumonia, and Japanese encephalitis.[15] The DHS plans to perform research at NBAF to study how these pathogens enter the animal, what types of cell the disease affects, what effects the disease has on cells and animals, and how newly developed countermeasures help the animal develop protection against the disease.

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[12] Pathogen biosafety levels and recommended protective measures at each biosafety level are developed by the Department of Health and Human Services (Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition, February 2007. Available online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm]). The BSL-3Ag containment level was established by the USDA for research with certain pathogens in large animal species (U.S. Department of Agriculture, Agricultural Research Service, *ARS Facilities Design Standards*, 242.1-M ARS, July 24, 2002. Available online at [http://www.afm.ars.usda.gov/ppweb/PDF/242-01M.pdf]).

[13] For example, Nipah virus research requires BSL-4 laboratories. Since the United States has limited space to perform large animal research under BSL-4 containment, U.S. scientists have gone outside the country, for example to Canada, to conduct such experiments. Testimony by James Roth, Director, Center for Food Security and Public Health, Iowa State University, before the Senate Committee on Agriculture, Nutrition, and Forestry, on July 20, 2005. Available online at [http://agriculture.senate.gov/Hearings/hearings.cfm?hearingid=1572&witnessId=4472].

[14] 71 *Fed. Reg.* 3107-3109 (January 19, 2006).

[15] Department of Homeland Security, *Facility Research & Staffing for the National Bio and Agro-Defense Facility*, June 12, 2007. Available online at [http://www.dhs.gov/xres/labs/gc_1181073261627.shtm].

NBAF Site Selection Process

The DHS stated that the establishment of NBAF would be a multi-stage process. This process involves:

- obtaining expressions of interest to be the site of NBAF;
- selecting prospective sites from these expressions of interest and requesting further information;
- assessing the information provided and visiting these prospective sites;
- narrowing the number of prospective sites to a list of final sites;
- preparing environmental impact studies of the final sites;
- choosing a site for NBAF; and
- constructing the facility.

This process is currently at the environmental impact study phase. The DHS stated it planned to choose the final site by October 2008.[16] However, DHS recently revised that prediction to December 2008.[17]

Expressions of Interest

In January 2006, DHS issued a Request for Expressions of Interest from consortia interested in hosting NBAF. Consortia responding to the DHS request included academia, industry, and non-profit institutes. In its request, DHS described four criteria that the agency would use when considering the expressions of interest:

- research capabilities,
- workforce,
- acquisition/construction/operating expertise, and
- community acceptance.[18]

Prospective Sites

In August 2006, DHS selected 18 sites from the 29 expressions of interest. These sites were required to submit more information with respect to the four criteria. One site was later removed from consideration by its sponsoring consortium. Although 17 sites were under consideration, only 12 consortia were involved, as some consortia submitted multiple possible sites that were selected by DHS (see

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[16] Testimony by John Vitko, Jr., Head, Chemical and Biological Division, Science and Technology Directorate, Department of Homeland Security, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[17] James Johnson, Office of National Laboratories, Science and Technology Directorate, Department of Homeland Security, Public statement at NBAF Draft Environmental Impact Statement Public Meeting, Washington, DC, July 24, 2008.

[18] 71 *Fed. Reg*. 3107-3109 (January 19, 2006).

Table 1).[19] An intergovernmental review group, which included DHS, USDA, the Department of Health and Human Services, and the Department of Defense, assessed the additional information. The DHS then visited each site to validate the information provided and to observe the sites.

Table 1. Consortia Selected by DHS after Expression of Interest

Consortium	Site Location
University of California/Lawrence Livermore National Laboratory	CA
Georgia Consortium for Health and Agro-Security (2 sites)	GA
Heartland BioAgro Consortium (2 sites)	KS
Kentucky and Tennessee NBAF Consortium	KY
Mid-Atlantic Bio-Ag Defense Consortium	MD
Gulf States Bio and Agro-Defense Consortium (3 sites)[a]	MS
University of Missouri at Columbia NBAF Consortium	MO
North Carolina Consortium for the NBAF	NC
Oklahoma State University Consortium	OK
Texas A&M University and the NBAF Consortium	TX
Texas Biological and Agro-Defense Consortium (3 sites)	TX
Wisconsin Consortium	WI

Source: DHS, online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].
a. One site was withdrawn from consideration in April 2007.

Finalists

Following the site visits, DHS selected five sites in July 2007 for further analysis. This analysis included preparation of a single Environmental Impact Statement (EIS) which evaluated all of the finalists. The DHS added Plum Island as a selected site, even though it had not participated in the earlier part of the selection process (see **Table 2**). Subsequent to the selection of the final sites, potential irregularities in the selection process were identified.[20] Some sites rated more positively were rejected in favor of sites with less positive ratings according to internal DHS documentation. The DHS asserted that the decision of which sites would become finalists was made based on factors beyond those considered in the described documentation, specifically highlighting the "unique contributions certain consortia committed to make."[21]

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[19] See online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].

[20] Larry Margasak, "NBAF Choices Suspect; Experts Ignored," Associated Press, August 10, 2008.

[21] Ibid.

The development of an EIS involved public hearings, comment periods, and an open docket for comments to be addressed in the draft EIS.[22] The DHS published the draft EIS in June 2008.[23] The DHS will consider comments received during the 60-day public comment period. Its responses to the public comments and other adjustments will be incorporated into its final EIS.

Table 2. Finalists for NBAF Site

Consortium	Location
Georgia Consortium for Health and Agro-Security	University of Georgia Athens, GA
Heartland BioAgro Consortium	Kansas State University Manhattan, KS
Gulf States Bio and Agro-Defense Consortium	Flora Industrial Park Madison County, MS
North Carolina Consortium for the NBAF	Umstead Research Farm Butner, NC
Texas Biological and Agro-Defense Consortium	Texas Research Park San Antonio, TX
Department of Homeland Security[a]	Plum Island, NY

Source: DHS, online at [http://www.dhs.gov/xres/labs/gc_1184180641312.shtm] and 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

a. According to DHS, although not included in the competitive selection process described above, the DHS-owned Plum Island will also be considered as a potential NBAF site.

Final Site Selection Criteria

The DHS expects to choose a site and publish the Record of Decision detailing its rationale in December 2008.[24] This decision will be based on the EIS and other completed analysis. Other studies and assessments DHS plans to use include: (1) Threat and Risk Assessment, (2) Site Cost Analysis, (3) Site Characterization Study, (4) Plum Island Facility Closure and Transition Cost Study; and (5) prior analysis of the alternative sites against DHS's site selection evaluation criteria.[25] A panel of government employees will consider the information in these reports and report its findings to the DHS Under Secretary for Science and Technology who will choose

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[22] Additional information on the potential sites and dates for public meetings about the EIS are available at 72 *Fed. Reg.* 41764-41765 (July 31, 2007) and 73 *Fed. Reg.* 36540-36542 (June 27, 2008).

[23] Available online at [http://www.dhs.gov/xres/labs/gc_1187734676776.shtm].

[24] James Johnson, Office of National Laboratories, Science and Technology Directorate, Department of Homeland Security, public statement at NBAF Draft Environmental Impact Statement Public Meeting, Washington, DC, July 24, 2008.

[25] 73 *Fed. Reg.* 36541 (June 27, 2008).

the site.[26] Although the criteria for siting NBAF have been described, the relative importance or weight of each factor has not been made public by DHS. For example, although the Draft EIS states the that the risk of a disease escaping from a facility on Plum Island and becoming established in the United States is lower than if NBAF is located on the mainland,[27] other factors such as its higher construction cost or local acceptance may outweigh this benefit. Although this process is not complete, reportedly some sites have already been excluded. For example, Members of Congress have reportedly been assured that DHS will not build NBAF on Plum Island; however DHS has not publicly acknowledged this decision.[28]

NBAF Funding

In the DHS Science and Technology FY2006 congressional budget justification, DHS provided a NBAF project schedule that included a summary of major milestones, a projected time line for meeting the milestones, and projected funding requirements by fiscal year to launch operation of a new facility in 2010 (see **Table 3**).

Table 3. Initially Projected NBAF Construction Funding Requirements (2005)

($ in millions)

FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	Total
3	23	73	129	129	94	451

Source: Department of Homeland Security, Science and Technology Directorate, *FY2006 Congressional Justification*.

Actual NBAF funding has not followed this schedule (see **Table 4**). The DHS has requested, and received, appropriations at a lower level than initially projected in 2005. The DHS Science and Technology FY2006 congressional budget justification stated that NBAF funding began in FY2005 when "$3 M was received for a planning and feasibility study from base funding of Biological Countermeasures."[29] However, DHS has subsequently clarified that the FY2005 funding was used elsewhere in DHS and that FY2006 and FY2007 appropriations

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[26] Department of Homeland Security, personal communication, August 18, 2008.

[27] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. ES-10.

[28] Matt Korade, "New York Lawmakers Glad to Be Included Out of Bio-Lab Sweepstakes," *CQ Homeland Security*, August 11, 2008.

[29] Department of Homeland Security, Science and Technology Directorate, *FY2006 Congressional Justification*, p. 45.

funded these studies.[30] In FY2006, Congress appropriated $23 million to select a site and conduct other pre-construction activities.[31] In FY2007, an additional $23 million was appropriated for site selection and other pre-construction activities.[32] The FY2007 DHS Appropriations Act also included a $125 million rescission of unobligated prior year appropriations from Science and Technology Directorate accounts. As part of its implementation of this law, DHS removed $11 million from the FY2006 NBAF appropriation.[33] In FY2008, Congress appropriated $11 million to continue environmental studies necessary to select a site for NBAF.[34] For FY2009, the President's budget requests $35.6 million to continue progress on NBAF construction.

Table 4. NBAF Construction Funding

($ in millions)

Action	FY2005	FY2006	FY2007	FY2008	FY2009
DHS Allocation	3				
DHS Reallocation	(3)				
P.L. 109-90		23			
P.L. 109-295		(11)	23		
P.L. 110-161				11	
FY2009 Budget Request					36
Total Annual Appropriations	**0**	**12**	**23**	**11**	
Annual Costs Projected in 2005 (from **Table 3**)	3	23	73	129	129

Source: Funding rounded to nearest million. CRS calculations based on DHS congressional budget justification, H.Rept. 109-241, H.Rept. 109-699, and DHS personal communication.

The DHS has changed the expected completion date for the NBAF facility from 2010 to 2015.[35] An updated full cost schedule is not publicly available. In the February 2005 projection, DHS anticipated requesting funding throughout the construction process, including 2010, the year DHS expected to open the facility. This raises questions about whether the total cost of the NBAF facility will increase

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[30] Department of Homeland Security, personal communication, September 10, 2007.

[31] H.Rept. 109-241 to accompany H.R. 2360 (P.L. 109-90), p. 78.

[32] H.Rept. 109-699 to accompany H.R. 5441 (P.L. 109-295), p. 168.

[33] Department of Homeland Security, personal communication, September 10, 2007.

[34] P.L. 110-161, *Consolidated Appropriations Act, 2008*.

[35] Department of Homeland Security, *Plum Island Animal Disease Center Facility Closure and Transition Study*, July 2008, p. 12.

due to the extension of the construction schedule. Subsequent DHS budget requests have not updated the projected overall funding requirements. It remains unclear how this delay is likely to affect the future annual appropriations requests and the total cost of the project.

The DHS *Science and Technology Five-Year Research Plan* projects NBAF costs to be $436.5 million for FY2007-FY2011.[36] Including the $12 million in FY2006 brings the cumulative total for FY2005-FY2011 to $448.5 million (see **Table 5**). The DHS did not include costs beyond FY2011 in this five year projection, although they predict construction to continue until 2014.

Table 5. Changing NBAF Funding Projections

($ in millions)

Year of Projection	FY05	FY06	FY07	FY08	FY09	FY10	FY11	Total
2005	3.0	23.0	73.0	129.0	129.0	94.0	0	451.0
2007	0[a]	12.0[a]	23.0	11.0	45.6	184.9	172.0	448.5[b]

Source: CRS calculations, Department of Homeland Security, Science and Technology Directorate, *FY2006 Congressional justification*; Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007; and DHS, personal communication September 10, 2007.

a. These numbers were not included in the DHS projection, but are taken from actual funding, see **Table 4**.

b. The DHS did not include costs beyond FY2011 in this five year projection, although they predict construction to continue until 2014.

The two DHS project schedules differ in the pace of anticipated funding requests. The initial NBAF project schedule indicated DHS was to receive the bulk of its appropriated construction funding in the years immediately before facility completion. In contrast, the funding schedule provided in the *Five-Year Research and Development Plan* indicated DHS would receive the bulk of NBAF construction funding up to four years prior to facility completion. The DHS may be attempting to account for NBAF's full funding requirements within the 2007 five-year plan.[37]

Site Specific and Additional Costs

In 2007, DHS stated that the overall construction cost will depend on the site selected and that site-specific infrastructure costs may increase the total cost above

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[36] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[37] The DHS states that no additional funds beyond those reported in the five year plan are expected to be requested, barring site-specific infrastructure costs. Department of Homeland Security, personal communication, September 10, 2007, and Department of Homeland Security, personal communication, October 4, 2007.

$451 million.[38] In 2008, DHS published site-specific construction cost estimates (see **Table 6**).[39]

Table 6. Site Specific Cost Estimates
($ in millions)

Cost Category	2005 Base line	MS	TX	NC	GA	KS	NY
Construction	390.0[a]	498.0	501.7	523.7	525.8	563.0	752.4
Other Costs[b]	61.0[c]	150.2	150.7	153.6	154.2	161.6	186.9
Total	**451.0**	**648.2**	**652.4**	**677.3**	**680.0**	**724.6**	**939.3**

Source: CRS calculations from DHS estimates. Department of Homeland Security, *National Bio and Agro-Defense Facility Site Cost Analysis*, July 2008.

a. This figure did not include site-specific improvements to infrastructure and other site-specific costs.
b. Includes planning, project development, technical document review, architectural/engineering costs, commissioning agents fees, and owner management contingency fees.
c. This figure did not include technical document review or owner management contingency fees.

The DHS cost analysis shows that the 2005 baseline has underestimated the total cost of the project. Site-specific cost estimates for construction, including infrastructure upgrades, are greater than the 2005 baseline by $108 million to $362.4 million. Other costs contributing to the total facility costs are greater than the baseline by $89.2 million to $125.9 million; in all cases at least double the 2005 baseline. Some of the increase in other costs reflects additional charges arising from services not originally included in the 2005 baseline.

Not included in these projected costs are equipment and relocation expenses involved in transferring the research projects of PIADC to NBAF.[40] These costs are variable, as they depend on the final location of NBAF, the number of research projects to be transferred, and the particular equipment needs identified. The DHS published a report describing how it determined these costs; however, the actual estimates were redacted from the public document.[41] These costs have been

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[38] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007 and Department of Homeland Security, personal communication, September 10, 2007.

[39] Department of Homeland Security, *National Bio and Agro-Defense Facility Site Cost Analysis*, July 2008. Available online at: [http://www.dhs.gov/xres/labs/gc_1187734676776.shtm].

[40] Similar move-in costs will be incurred following the completion of the NBACC facility. Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

[41] Department of Homeland Security, *Plum Island Animal Disease Center Facility Closure*
(continued...)

reportedly estimated by DHS as up to $100 million.[42] However, DHS noted in 2007 that building NBAF at the Plum Island site would produce "substantially lower transition activity costs."[43] These costs might be seen as partially offsetting the higher estimated construction costs of building NBAF on Plum Island (see **Table 6**). Additional delays to the construction schedule may further change the final cost of the facility due to changing material and labor costs.[44]

Building on the mainland would allow DHS to sell Plum Island to possibly recoup some of the costs of NBAF construction (see **Selling Plum Island** below). However, before DHS could sell Plum Island, the site would require extensive decontamination and remediation. The DHS has estimated these costs but it has not publicly released its estimate.[45]

Policy Issues

Policy issues relating to NBAF include uncertainties about the consequences of a pathogen release from the facility, adequacy of response plans, adequacy of protection against pathogen release, whether it is safe to build the facility on the mainland, the need for, and scope of NBAF, coordination among agencies, the NBAF construction schedule, disposition of PIADC and Plum Island, and community concerns.

The 110th Congress has considered some legislation relating to some of these issues. The Food, Conservation, and Energy Act of 2008 (P.L. 110-246, also referred to as the 2008 farm bill) would allow DHS to possess live FMD virus on the U.S.

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[41] (...continued)
and Transition Study, July 2008. DHS declined to provide CRS an unredacted version of this document. DHS stated that to do so might put the Department at a disadvantage during cost negotiations with contractors to perform work described in the report. DHS, personal communication, September 24, 2008.

[42] As cited in *Letter from Marc L. Kesselman, U.S. Department of Agriculture, to Representatives John D. Dingell and Bart Stupak*, December 18, 2007.

[43] Department of Homeland Security, *Plum Island Animal Disease Center Facility Closure and Transition Study*, July 2008, p. 34.

[44] Material and labor costs may be higher or lower at the time of construction than at the time of the initial projection. An increase in total cost due to increased material expense occurred during construction of another DHS high containment biological laboratory, the National Biodefense Analysis and Countermeasures Center. See CRS Report RL32891, *The National Biodefense Analysis and Countermeasures Center: Issues for Congress*, by Dana A. Shea.

[45] Department of Homeland Security, *Plum Island Animal Disease Center Facility Closure and Transition Study*, July 2008. The DHS publicly released a redacted copy of this study, removing cost estimates. DHS declined to provide CRS an unredacted version of this document. DHS stated that to do so might put the Department at a disadvantage during cost negotiations with contractors to perform work described in the report. DHS, personal communication, September 24, 2008.

mainland. Before passing the farm bill provision, Congress also considered permitting FMD research on the mainland through H.R. 1717. The FY2009 DHS appropriations bills contain language that would either authorize or require the sale of Plum Island if DHS selects a mainland site for NBAF (as of this date, H.R. 6947 and S. 3181, respectively). As reported by the House Committee for Appropriations, the Department of Homeland Security Appropriations Act, 2009 (H.R. 6947) would forbid the use of FY2009 appropriated funds for design or construction of NBAF on the mainland until the DHS completes a risk analysis of whether foot-and-mouth disease work can be done safely on the United States mainland and until the Government Accountability Office (GAO) reviews this risk assessment.

Consequences of a Pathogen Release

Although the likelihood of a pathogen release is low, pathogens have escaped from high containment laboratories through accidental releases. The potential consequences of such a release vary widely, since the effects would depend on the pathogen type; amount, location, and method of release; weather conditions; presence of susceptible nearby humans or animals; and the effectiveness of any government and private sector response. Since NBAF will store pathogens known to have significant animal health impact, the consequences of a pathogen release has been a topic of great interest.

The draft EIS addresses the consequences of a foreign animal disease pathogen release from NBAF at the different candidate locations. Although some of the pathogens evaluated to be studied at NBAF can cause human disease, the draft EIS analysis focuses on economic losses following a pathogen release rather than modeling the effect on public health effects. The analysis presented relies on a "limited" model to estimate the economic effects of a release of three of the pathogens (foot and mouth disease virus, Rift Valley fever virus, and Nipah virus) planned to be studied at NBAF.[46] DHS chose these pathogens for analysis in the EIS because DHS considered them representative of all of the pathogens to be studied at NBAF. Attempts to calculate or model the effects of a disease outbreak are complicated and have produced differing results. In 2008, the USDA developed a complex economic model to estimate the costs associated with outbreaks of foreign animal diseases.[47] Whether the results of this model, which has not been applied to all of the pathogens to be stored at NBAF, are in accord with those used in the draft EIS may shed light on the efficacy of the draft EIS release consequence assessment.

Foot and Mouth Disease. Foot and Mouth disease (FMD) is a highly contagious disease that affects cloven-hoofed animals including cattle, pigs, deer, sheep, and bison. The only known human infections resulted from laboratory-

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[46] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. D-8.

[47] Philip Paarlberg, Ann Seitzinger, John Lee, and Kenneth Mathews, Jr., "Economic Impacts of Foreign Animal Disease," *Economic Research Report Number 57*, May 2008.

acquired infections.[48] An outbreak on the mainland would likely cause severe disruption in the nation's export markets.

Several groups have attempted to estimate the cost of an outbreak of FMD either through an agroterrorist attack or an accidental release. A University of California study in 1999 estimated the potential impacts of an FMD outbreak in California at between $8.5 and $13.5 billion.[49] A 2002 Purdue University and USDA study found that an FMD outbreak in the United States similar to the 2001 outbreak in the United Kingdom could reduce farm income by $14 billion. A 2002 National Defense University study estimated that a limited outbreak of FMD on just 10 farms could have a $2 billion financial impact.[50] The USDA used FMD to illustrate the use of their complex economic model and determined an FMD outbreak would cost between $2.8 billion and $4.1 billion.[51] This estimate correlates closely with the estimate generated for the draft EIS which indicated an accidental FMD release from NBAF would cost between $2.8 billion (Plum Island) and $4.2 billion (Kansas).[52]

Rift Valley Fever. Rift Valley fever is a disease that affects humans and many domesticated animals including sheep, cattle, goats, and dogs. Approximately 8% of infected people become severely ill. Its fatality rate in humans depends on many factors including strain of the virus and underlying health of the patient but is generally considered to be approximately 1%.[53] This disease is transmitted through mosquito bite or through handling infected animals.

The draft EIS does not contain an independent estimate of the cost of a release of the Rift Valley fever virus from NBAF. Rather it cites a 2004 estimate from the Rift Valley Working Group, a group of government and nongovernment experts. This group estimated the impact of a deliberate release at multiple locations on the U.S. economy as $50 billion.[54] In contrast to FMD and as previously noted, Rift

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[48] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. D-3.

[49] Beth Lautner and Steve R. Meyer, "U.S. Agriculture in Context: Sector's Importance to the American Economy and Its Role in Global Trade," in Terrence K. Kelly, Peter Chalk, James Bonomo, John Parachini, Brian A. Jackson, and Gary Cecchine, *The Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock*, CF-193-OSTP, 2004, pp. 111, 113-114. Available online at [http://www.rand.org/pubs/conf_proceedings/2005/CF193.pdf]).

[50] Henry S. Parker, *Agricultural Bioterrorism: A Federal Strategy to Meet the Threat*, McNair Paper 65, National Defense University, March 2002. Available online at [http://www.ndu.edu/inss/McNair/mcnair65/McN_65.pdf].

[51] Philip Paarlberg, Ann Seitzinger, John Lee, and Kenneth Mathews Jr., "Economic Impacts of Foreign Animal Disease," *Economic Research Report Number 57*, May 2008.

[52] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. D-9.

[53] CDC, "Rift Valley Fever Outbreak - Kenya, November 2006 — January 2007," *Morbidity and Mortality Weekly Report*, February 2, 2007, p. 73-76.

[54] ANSER, *Rift Valley Fever Working Group: Summary Report and Recommendations*, (continued...)

Valley fever can infect and kill humans. The Rift Valley Working Group estimated that the scenario they studied would result in 114 human deaths within the first year following the attack. In the draft EIS, DHS concludes that because Rift Valley fever could become endemic in the United States following a release from NBAF, the cost of a release could "approach the levels projected by the RVF Working Group."[55] The DHS did not differentiate costs of a release from each of the proposed sites. The draft EIS does state that a release from the Plum Island site or the Kansas site is less likely to result in Rift Valley fever becoming an endemic disease and thus represents a smaller threat to the national economy.[56]

Nipah Virus. Nipah virus is a serious disease that affects humans and some domesticated animals including pigs, cats, dogs, cattle, goats, and horses. The mortality rate varies for humans varies by outbreak but approximately 40% of infected humans die. Nipah virus is not easily transmissible from person to person, but people with close contact with sick people, animals, or infected tissues can become infected.[57]

The draft EIS estimated a release of Nipah virus from NBAF would cost the pig industry $19 million.[58] Although Nipah virus can kill humans, DHS did not estimate the potential number of lives lost due to a Nipah virus release from NBAF in the draft EIS. The DHS did not differentiate costs of a release from each of the proposed sites, although the draft EIS states the Plum Island's relative isolation from susceptible livestock would lower the risk to the regional and national economy.[59]

Adequacy of Response Plans

Given the potential consequences associated with a pathogen release from NBAF, policymakers may question the adequacy of the government's planned response to a release. The USDA responded to previous releases of FMD on Plum Island and has developed a plan to contain an outbreak from a mainland site. According to USDA, the plan accounts for many factors, including the size of the outbreak, how the outbreak was detected, and local circumstances. The plan includes

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[54] (...continued)
August 24-26, 2004. Available online at [http://nabc.ksu.edu/assets/factsheet_docs/rvf/rift%20valley%20report.pdf].

[55] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. D16.

[56] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. D-15.

[57] Vincent Hsu, *et al.* "Nipah Virus Encephalitis Reemergence, Bangladesh." *Emerging Infectious Disease*, December 2004, pp. 2082-2087.

[58] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. D-21.

[59] Ibid., p. D-22.

eradication of all potentially infected wildlife.[60] The federal government may be less well prepared to contain other diseases it plans to study at NBAF. In August 2007, the USDA and the Rift Valley Fever Working Group noted that the federal government lacked a single comprehensive response plan for a Rift Valley fever (RVF) outbreak. Furthermore, the authors asserted:

> The United States has national and state assets for vector surveillance, but none for vector control. In the event of an RVF outbreak, we would have to rely on cooperation from local mosquito abatement agencies that may or may not be distributed where they are most needed. The US military has the logistic capability to perform vector control anywhere in the country and has done so on a case-by-case basis, but no agreements or even discussions have taken place to make the military part of a vector-borne disease response plan.[61]

In more recent meetings, the Rift Valley Working Group has noted that the federal government is making some progress addressing these needs.[62] Although NBAF will not commence research for several years, policymakers might decide that response plans should be fully evaluated and in place before NBAF begins operations. The viability and cost of the response plans might differ between the alternative NBAF sites and influence the final choice. For example, responding to a release from a site surrounded by potential wildlife or livestock animal disease hosts could be more expensive than from a site that was not.

Adequacy of Protection Against Pathogen Release

A pathogen release is a potential risk at all high-biocontainment laboratories. Biosafety guidelines and the Select Agent Program have been implemented to help reduce the probability that a pathogen might be released from a laboratory. Thus the likelihood that a pathogen would be accidentally released from the laboratory into the surrounding area is generally considered to be low.

Biosafety Guidelines. To protect against an accidental pathogen release or an occupational exposure to a laboratory worker, the Department of Health and Human Services and the USDA have developed guidelines for the construction, maintenance, and operation of high-biocontainment laboratories. These guidelines take into account the properties of the pathogen and the types of experiments being performed. The established biocontainment levels have increasing levels of rigor, and these biocontainment protocols are adhered to as a matter of best practice in government, academic, and industrial laboratories.[63]

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[60] Bill White, USDA, Public statement at NBAF Draft Environmental Impact Statement Public Meeting, Washington DC, July 24, 2008.

[61] Seth Britch, Kenneth Linthicum, and the Rift Valley Fever Working Group, "Developing a Research Agenda and a Comprehensive National Prevention and Response Plan for Rift Valley Fever in the United States," *Emerging Infectious Diseases*, Volume 13, Number 8, August 2007. Available online at [http://www.cdc.gov/EID/content/13/8/e1.htm].

[62] USDA, personal communication, August 18, 2008.

[63] Centers for Disease Control and Prevention and National Institutes of Health, Department (continued...)

Despite these physical barriers, accidental releases and occupational exposures have happened at high containment laboratories. The GAO documented multiple examples of FMD being found outside of laboratory high containment areas worldwide including several at the PIADC.[64] Since 2004, laboratory workers in the United States have been exposed to several pathogens including those that cause tularemia, Ebola, anthrax, Q fever, and Brucellosis.[65]

Security concerns regarding the potential for terrorist use of pathogens also has led to the application of registration of researchers and facilities that work with or possess certain "select agents." The PIADC must conform to the regulations of the Agricultural Select Agent Program promulgated by USDA, and the NBAF would as well.[66] Under these regulations, pathogens and toxins that pose a severe threat to public, animal, or plant health have been identified and listed as "select agents." Agricultural select agents are pathogens and toxins, including FMD, that pose a severe threat to animal or plant health. Entities that possess, use, or transfer these select agents are required to develop security plans for protecting the select agents, register with the USDA Animal and Plant Health Inspection Service (APHIS), and become certified as eligible to possess select agents. Researchers handling select agents must pass a security review by the Department of Justice.

Even with these guidelines and regulations in place, some critics remain concerned that these protections may be insufficient.[67] Government investigations have found many examples of laboratories not complying with the select agent rules. In a 2006 report, the HHS Inspector General found that 11 of 15 representative universities that it investigated had not fully complied with the select agent regulations.[68] It also found that none of the eight representative state, local, private, or commercial laboratories that it investigated were in full compliance with the select

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[63] (...continued)
of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5th Edition, February 2007, online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf].

[64] Government Accountability Office, *High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland*, GAO-08-821T, May 22, 2008.

[65] Jocelyn Kaiser, "Accidents Spur a Closer Look at Risks at Biodefense Labs," *Science*, September 28, 2007, p. 1852.

[66] The agricultural select agent regulations are codified at 9 C.F.R. 121 and 7 C.F.R. 331. A comparable program exists for select agents that might infect humans. It is overseen by the Centers for Disease Control and Prevention on behalf of the Department of Health and Human Services. These select agent regulations are codified at 42 C.F.R. 73.

[67] For example, see Edward Hammond, Director, The Sunshine Project, testimony before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

[68] See Department of Health and Human Services, Office of Inspector General, *Summary Report on Universities' Compliance with Select Agent Regulations*, A-04-05-02006, June 2006; and Department of Health and Human Services, Office of Inspector General, *Summary Report on Select Agent Security at Universities*, A-04-04-02000, March 2004.

agent regulations. The USDA Inspector General similarly found compliance problems.[69] Such violations have led to the levying of $1,837,000 in fines and the suspension of permission of one laboratory's permission to use select agents.[70]

Should NBAF Be on the Mainland?

Historically, in the United States, foreign animal disease has been studied on an island separated from the mainland because of concerns that the disease pathogens might infect animals and spread through domestic wildlife and livestock. As biocontainment technology has increased in sophistication, questions have been raised whether such research could now be performed safely on the mainland. Additionally, questions have been raised about the efficacy of a water barrier in preventing animals from swimming to the island and whether pathogens could be carried by air from an island to the mainland. In the current context, policymakers face a tradeoff between a potentially increased risk of infection following a pathogen release versus lower construction, operating, and maintenance costs and greater efficiency and ease of access.

According to DHS, a pathogen release from a laboratory on the mainland would cause greater harm than a equivalent release from a laboratory on Plum Island. The DHS noted that "with the exception of Plum Island, each of the proposed sites resides in an area where the wildlife, vegetation, agriculture, and human populations provide ample opportunity for each of the viruses (FMDV, RVFV, and Nipah virus) to become established and spread once released from NBAF."[71] Largely because of this risk, only the Plum Island site qualified for the "low" site-specific risk category while the other sites were deemed "moderate" risk.[72] In congressional testimony, DHS has stated that modern biocontainment technology is sufficient to prevent an accidental release.[73] However, in the EIS, DHS noted that despite "improved engineering and design of high-biocontainment biological laboratories, accidents due to human error or maintenance failures ... could cause releases," and described three such incidents since 2006.[74]

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[69] See Department of Agriculture, Office of Inspector General, *Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations — Phase I*, Report No. 33601-2-AT, June 2005; and Department of Agriculture, Office of Inspector General, *Animal and Plant Health Inspection Service Evaluation of the Implementation of the Select Agent or Toxin Regulations — Phase II*, Report No. 33601-3-AT, January 2006.

[70] See online at [http://oig.hhs.gov/fraud/enforcement/administrative/cmp/cmpitems.html].

[71] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, June 2008, p. 3-442.

[72] Ibid. Table 3.14.4-7, p. 3-441.

[73] See, for example, oral testimony of John Vitko, Head, Chemical and Biological Division, Science and Technology Directorate, DHS, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[74] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft* (continued...)

Some analysts and foreign governments have concluded that research on certain agricultural pathogens should only be done in geographically isolated laboratories.[75] According to the GAO, when the governments of Denmark and Germany faced the same question of whether to build new foot and mouth disease laboratories on the mainland or to replace aging island laboratory infrastructure, both decided to keep the laboratories on islands.[76] The government of Australia chose to contract its research using live FMD virus to locations in other countries. In contrast, FMD research is conducted in a mainland laboratory in Canada.[77]

Permission to Work with Foot and Mouth Disease. Despite the potentially higher costs of a Rift Valley fever virus release, in terms of economic costs and human lives lost,[78] most of the debate about mainland versus island laboratories has focused on FMD. This likely arises in part from the legal restrictions placed on such research. Currently, research on live FMD virus is statutorily limited to locations outside of the mainland of the United States. Only if the Secretary of Agriculture provides an explicit permit under 21 U.S.C. 113a may research on live FMD virus be performed on the mainland of the United States.[79]

The GAO concluded that DHS has not performed the necessary analysis to determine whether it is possible to safely perform FMD research on the mainland.[80] As reported by the House Committee for Appropriations, the Department of Homeland Security Appropriations Act, 2009 (H.R. 6947) contains language forbidding the use of FY2009 appropriated funds for the

> design and construction of a National Bio and Agro-defense Facility located on the United States mainland until the Secretary of Homeland Security completes

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[74] (...continued)
Environmental Impact Statement, June 2008, p. 3-364.

[75] Emily Ramshaw, "Texas May Be Home to New Foot-and-mouth Disease Research Lab," *Dallas Morning News*, November 11, 2007.

[76] Government Accountability Office, *High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland*, GAO-08-821T, May 22, 2008, p. 5.

[77] It could be argued that this laboratory's downtown location isolates it from susceptible animals. Ibid.

[78] Department of Homeland Security, *National Bio and Agro-Defense Facility Draft Environmental Impact Statement*, Section D, June 2008. Available online at: [http://www.dhs.gov/xres/labs/gc_1187734676776.shtm].

[79] Because of concerns about the economic damage that might arise from the release of the pathogen that causes foot and mouth disease into domestic animal stocks, Congress enacted prohibitions in 1948 against performing research within the mainland of the United States. 21 U.S.C. 113a prohibits the Secretary of Agriculture from introducing live foot and mouth disease virus to the mainland of the United States unless the Secretary determines it is necessary and in the public interest.

[80] Government Accountability Office, *High-Containment Biosafety Laboratories: DHS Lacks Evidence to Conclude That Foot-and-Mouth Disease Research Can Be Done Safely on the U.S. Mainland*, GAO-08-821T, May 22, 2008.

a risk analysis of whether foot-and-mouth disease work can be done safely on the United States mainland and this risk assessment is reviewed by the Government Accountability Office.

When PIADC was transferred to DHS, the Secretary of Agriculture retained the authority to prevent FMD research from being performed on the mainland of the United States. If NBAF is located on the mainland of the United States and is to perform high-value foreign animal disease research, researchers at the facility will likely need to receive such permission from the Secretary of Agriculture to perform FMD research.[81] While some experts might construe this permission as a formality, since, under HSPD-9, DHS and USDA are to coordinate their activities in food and animal disease research, others might see it as a potential barrier to effective and efficient use of NBAF.

The Food, Conservation, and Energy Act of 2008 (P.L. 110-246). On June 18, 2008, the Food, Conservation, and Energy Act of 2008 (also referred to as the 2008 farm bill) was enacted with a provision (section 7524) that requires USDA to issue a permit to DHS for live FMD virus research at one successor facility to the PIADC. The provision states that, once issued, the permit can only be suspended, revoked, or otherwise impaired if the Secretary of Agriculture determines that the FMD research is not being carried out in compliance with the select agent regulations. This provision preserves the restrictions on FMD research that have existed in 21 U.S.C. 113a — including USDA's authority to control possession — but provides one exception to allow DHS to possess and work with the virus.

H.R. 1717. Before the 2008 farm bill was enacted, the House Committee on Homeland Security debated a bill addressing FMD possession. As reported, H.R. 1717 would have instructed USDA to issue a permit to DHS for FMD research at NBAF. Other existing requirements under the agricultural select agent regulations would have continued to apply, and DHS would have had to meet them for the permit to remain valid. This is the basic provision that was adopted by the farm bill. H.R. 1717, as introduced, would have given DHS independent authority to possess FMD virus, notwithstanding 21 U.S.C. 113a.[82]

Need for and Scope of NBAF

Other agencies and organizations in addition to DHS have identified needs that could be met by NBAF. At least as early as 1999, USDA recognized a need for a BSL-4 facility capable of handling large animals. In response to a mandate by

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[81] The Administrator of the Agricultural Research Service, Department of Agriculture, has testified, "It is our expectation that the Secretary of Agriculture will authorize FMD work to be done on the mainland in NBAF, and that would be for all agencies. The USDA programs now at Plum Island will be a component of the NBAF facility. So yes, the Secretary of Agriculture intends to do that." See testimony by Edward Knipling, Administrator, Agricultural Research Service, Department of Agriculture, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007.

[82] See footnote 79.

Congress,[83] USDA commissioned a strategic planning task force that recommended that the "Agricultural Research Service must consider upgrading current Level 2 and Level 3 bio-containment units for animals and constructing a Level 4 unit."[84] In 2005, the National Research Council (NRC) echoed the need for a BSL-4 facility capable of handling large animals. The NRC also concluded that PIADC was at the end of its life cycle and that it should be "replaced urgently."[85]

While USDA and DHS have repeatedly stated their need for a new BSL-4 facility, neither department has publicly detailed how they determined their space requirements for this facility. In response to questions for the hearing record, DHS asserted that:

> Site criteria and requirements for NBAF were developed by an interagency technical working group, including DHS, USDA, and HHS to evaluate sites that would best support research in high-consequence animal and zoonotic diseases in support of Homeland Security Presidential Directives, HSPD-9 and HSPD-10.[86]

The DHS has not publicly released supporting documentation relating to the working group's deliberations.

The DHS projects the size of NBAF to be approximately 504,000 gross square feet.[87] Approximately 55,000 gross square feet of the facility would be BSL-4 laboratory space (see **Table 7**). This facility would be more than twice as large as the existing PIADC facility.[88] This sizeable increase in laboratory capacity may meet the requirements put forth by HSPD-9, as well as establishing the expanded, modern facilities to replace PIADC and perform necessary research activities. Full use of this expanded laboratory space may pose a challenge to federal research planners as other

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[83] P.L. 104-127, Subtitle D, section 884.

[84] USDA, *Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations*, August 1999, p. 24.

[85] National Research Council, *Critical Needs for Research in Veterinary Science*, (National Academies Press: Washington, DC) 2005.

[86] House Committee on Science, *An Overview of the Federal R&D Budget for Fiscal Year 2007*, Committee Serial No. 109-35, February 15, 2006.

[87] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*. The NBAF was initially estimated at 500,000 square feet with ten percent being BSL-4 laboratory space. 71 *Fed. Reg*. 3107-3109 (January 19, 2006). Other scoping documents place the size of the NBAF at 520,000 square feet. See online at [http://www.dhs.gov/xlibrary/assets/nbaf-scopingmeetingmaterials.pdf].

[88] PIADC has a combined office/laboratory space of 226,560 square feet, excluding other buildings. USDA, *Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations*, August 1999.

federal agencies have also expanded their research laboratory capacity, including BSL-3Ag space, providing alternative venues for performing such research.[89]

Table 7. Estimated Use of NBAF Space by Gross Square Footage

Space	Gross Square Footage
Office/Administrative	35,000
BSL-2	30,000
BSL-3	372,000
BSL-4	55,000
Vaccine Production	12,000
Total	504,000

Source: Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.
Note: BSL-2 space includes laboratory and support areas. BSL-3 space includes laboratory, agriculture threat containment, and training and support areas.

The ability of DHS to effectively use the newly constructed BSL-4 and BSL-3Ag laboratories may depend on efficient interagency cooperation in order to identify other agency research activities that could benefit from being performed at NBAF. The DHS and USDA investment into research areas done currently at PIADC may also need to increase to fill the expanded capacity. Analytic study assessing the current and future needs for BSL-3Ag and BSL-4 research may aid DHS and USDA in effectively using NBAF.

Coordination of Research Activities with Other Agencies

Since NBAF would replace PIADC, research at NBAF is expected to be collaborative between USDA and DHS. At PIADC, DHS and USDA cooperatively set research priorities, based on risk assessment and other information. Generally, USDA performs basic research activities while DHS develops the results of that research and attempts to translate them into practical applications.[90] However, since NBAF also represents an expansion in capacity and capabilities over PIADC, this relationship may change. Establishment of the new facility provides an opportunity to evaluate previous agreements and make adjustments. Assignment of lab space to

[89] For example, USDA has invested in expanded BSL-3Ag laboratories at both the National Wildlife Research Center in Fort Collins, Colorado, and the National Centers for Epidemiology and Animal Health in Ames, Iowa.

[90] For further discussion of how USDA and DHS cooperate at PIADC, see Government Accountability Office, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132, December 2005.

the Department of Health and Human Services or other agencies may require reevaluation and updates to these procedures.[91]

The USDA and DHS have testified that their current agreements have served them well at PIADC, with respect to both daily operation and transfer of technical information regarding research results and priorities.[92] Such interagency coordination may be essential in case of a crisis or in dealing with an outbreak of animal disease. The extent to which all agencies engaged in NBAF agree on how to coordinate roles and responsibilities may prove to be a key factor in maintaining clear lines of authority and information and may be crucial to effective oversight of the facility.

The 110th Congress is considering these issues. Under H.R. 1717 (reported by the House Homeland Security Committee on August 1, 2008), NBAF would be run by a director appointed by DHS in consultation with USDA. The director's role would be limited to operating and maintaining the facility, including ensuring security and emergency response plans. This role is less broad than in a previous version of the bill, which would have also given the DHS-appointed director authority over all research programming at the facility, including USDA research. In the committee-amended bill, in addition to the director, separate directors of research would be appointed from DHS and USDA to oversee the research programs of each department. The USDA and DHS would develop a "joint strategy" defining the roles of USDA and DHS at NBAF.[93]

Timeliness of Construction Activities

When complete, NBAF would eventually house all research activities underway at PIADC. The DHS considers PIADC to be approaching the end of its design lifetime. Finishing construction of NBAF and achieving operational status before down-sizing or decommissioning PIADC is dependent on timely construction activity. Because of the unique research currently performed at PIADC, the smooth transition of this capacity may be an issue of congressional concern. Beyond the

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[91] Because of NBAF's focus on foreign animal disease, agencies beyond USDA and DHS may have limited roles. Department of Homeland Security, personal communication, September 17, 2007.

[92] House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, "Reducing Threats to Our Nation's Agriculture: Authorizing a National Bio and Agro-Defense Facility," *Hearing Transcript*, May 23, 2007.

[93] In 2004, the USDA and DHS developed "A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs" to coordinate their activities with respect to activities at PIADC. While this strategy has not been made public by DHS or USDA, it has been discussed in congressional testimony. See testimony by Edward Knipling, Administrator, Agricultural Research Service, Department of Agriculture, before the House Committee on Homeland Security, Subcommittee on Emerging Threats, Cybersecurity, and Science and Technology, on May 23, 2007. The DHS has not updated this strategy. Department of Homeland Security, personal communication, September 17, 2007.

transition of research projects, programs, and supplies, transfer of personnel and retention of an experienced workforce may also pose a challenge to DHS and USDA.

The original schedule for NBAF, as presented to Congress, proposed finishing construction and commissioning NBAF in FY2010. Since then, the proposed schedule has been extended several times. In June 2006, DHS estimated NBAF operations would begin in 2013.[94] Until February 2008, the DHS website indicated that operations would begin in 2013 or 2014.[95] In July 2008, DHS estimated NBAF would be completed by January 1, 2015.[96]

The extension of the NBAF construction schedule increases the time that PIADC will be in operation. The PIADC has historically had security, coordination, and other issues.[97] The DHS has developed and implemented a multi-year *Corrective Action Plan* to address these issues and maintain the operation of PIADC.[98] Since PIADC has been identified as approaching the end of its design lifetime, extended operation and maintenance of these facilities may not be as cost effective or as efficient for the research endeavor as completing and transitioning research to NBAF. The DHS spent approximately $24 million in FY2007 and $17 million in FY2008 to upgrade the facilities at PIADC. The DHS did not request additional appropriation for upgrades in FY2009[99] and does not plan to in future years.[100] The upgrades include designing a new animal wing and continuing activities described in the *Corrective Action Plan*. The DHS expects completion of these upgrades in FY2010.[101] Further NBAF construction delays may require additional funds be used to support PIADC's corrective maintenance.

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[94] See online at [http://www.dhs.gov/xlibrary/assets/NBAF_Timeline.pdf].

[95] This web page has been subsequently modified to remove reference to completion date. See online at [http://www.dhs.gov/xres/labs/gc_1170798884583.shtm].

[96] Department of Homeland Security, *Plum Island Animal Disease Center Facility Closure and Transition Study*, July 2008, p. 12.

[97] See General Accounting Office, *Combating Bioterrorism: Actions Needed to Improve Security at Plum Island Animal Disease Center*, GAO-03-847, September 2003; and Government Accountability Office, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*, GAO-06-132, December 2005.

[98] According to DHS, the total cost of the *Corrective Action Plan* is approximately $56 million. The *Corrective Action Plan* was reported to Congress by DHS in FY2005. Department of Homeland Security, Office of Inspector General, *Additional Physical, System, and Management Controls Can Enhance Security at Plum Island (Redacted)*, OIG-07-43, May 2007.

[99] Department of Homeland Security, Science and Technology Directorate, *Fiscal Year 2009 Congressional Justification*.

[100] Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2007-2011*, May 2007.

[101] Ibid.

Future Use of PIADC

The DHS has yet to determine what will happen to the PIADC when construction of NBAF is completed. The DHS has stated that one of the main goals of NBAF is to expand upon the existing PIADC research. According to DHS, once NBAF is operational, PIADC research activities will transfer to it.[102]

The fate of the PIADC, once current research activities are transferred from it, remains unclear. The DHS has stated that "proper decontamination and decommissioning (D&D) of the facility after the transition will be critical to meet regulatory compliance and eventual disposal of the site."[103] The DHS has not stated when or how this process might occur. In discussing the development and construction of NBAF, DHS has stated, with regards to PIADC, that "no decision has been made as to the future of Plum Island."[104]

The DHS is currently investing money to improve and upgrade the laboratory facilities. Continued use of PIADC either by DHS in some other capacity or under the control of some other entity remains an option. Alternatively, following decommissioning, the laboratories might be removed and the site used for a different purpose. Although many local officials have opposed expanding the number or type of pathogens researched at PIADC, some have expressed support for the continued operation and existence of the facility, because of its economic value to the surrounding area.[105]

Selling Plum Island. One option proposed by DHS has been to sell Plum Island and use the profit from such a sale to offset the construction costs of NBAF, the decontamination and remediation costs for the island, and the demolition costs for the PIADC. Under this proposal, DHS would sell Plum Island in FY2009 or FY2010, arrange with the purchaser to allow operations to continue until NBAF construction was finished, and transfer Plum Island to the purchaser only after clean up of the island had been completed.[106]

Most sales of surplus property are handled by the General Services Administration (GSA) and any funds received directed to the Treasury.[107] The DHS has proposed adding statutory language to the FY2009 DHS appropriations act providing authority to liquidate the Plum Island assets and retain the proceeds of the sale. The proposed language indicates that these funds could be used to offset costs

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[102] Ibid.

[103] Ibid.

[104] Bill Bleyer, "Homeland Security Seeks Input on Plum Island Disease Lab," *Newsday*, August 21, 2007.

[105] Ibid.

[106] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

[107] For a brief overview, see CRS Report RS20630, *Disposition of Surplus Federal Property*, by Clay H. Wellborn.

associated with NBAF construction; however, the proposed language would also allow the DHS Secretary to use the net proceeds of the Plum Island sale for "other real property capital asset needs."[108] Under this proposed language, the net proceeds from the sale of Plum Island would be retained by DHS until fully spent rather than reverting to the Treasury at a future date.

The Senate version of the DHS FY2009 appropriations bill (S. 3181) has language similar to the DHS proposal. If the DHS Secretary chooses a site other than Plum Island for NBAF, Section 547 would require the Secretary to sell Plum Island through GSA. The proceeds of such a sale would be

> deposited as offsetting collections into the Department of Homeland Security Science and Technology "Research, Development, Acquisition, and Operations" account and, subject to appropriation, shall be available until expended, for site acquisition, construction, and costs related to the construction of the National Bio and Agro-defense Facility, including the costs associated with the sale, including due diligence requirements, necessary environmental remediation at Plum Island, and reimbursement of expenses incurred by the General Services Administration which shall not exceed 1 percent of the sale price.

The House version of the DHS FY2009 appropriations bill (H.R. 6947) also contains language similar to the DHS proposal. If the DHS Secretary chooses a site other than Plum Island for NBAF, Section 527 would authorize the Secretary to sell Plum Island through GSA. The proceeds of such a sale would be

> deposited into a separate account that shall be available, along with any other available appropriations for use by the Secretary in the acquisition of the site for and the construction of the National Bio and Agro-defense Facility: *Provided further*, That the Secretary may use such gross proceeds of sale to reimburse any fund of the Secretary used to pay for the costs associated with the sale, including due diligence requirements, necessary environmental remediation, and reimbursement of expenses incurred by the General Services Administration which shall not exceed 1 percent of the sale price: *Provided further,* That the net proceeds remaining after such use shall be available to the Secretary for design and construction of a new Department of Homeland Security headquarters facility, excluding daily operations and maintenance costs: *Provided further*, That the proceeds derived from the sale shall be available to the Secretary without further appropriation until expended and subject to approval pursuant to section 503 of this Act.

The application of the DHS proposal in the Senate and draft House bill have slightly different outcomes. In the Senate bill, the Secretary is required to sell Plum Island, while in the House bill the Secretary is authorized to sell Plum Island. In the Senate bill, any remaining proceeds would become part of the S&T Directorate's appropriated budget, while the House bill would allow the Secretary discretion in the further allocation of any remaining proceeds.

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[108] Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

The amount of money that might result from liquidation of the Plum Island assets is uncertain. Variations in remediation costs for environmental clean-up of the island and fluctuations in property values, for example, contribute sizeable uncertainties to any estimate of a future sale's proceeds. The sale might provide net funds insufficient for NBAF construction or might provide substantial surplus funds even after NBAF construction is complete. Also, a mismatch may arise between when the construction costs are incurred and when DHS would receive money from the sale. Additionally, the remediation and decontamination costs may need to occur prior to the sale, if no buyer is willing to purchase Plum Island in its unremediated state.

Congressional policymakers may weigh the value of having such offsetting revenue for current and future DHS construction against the potential for lessened appropriations-related oversight of DHS capital construction projects. By providing such authority, Congress may be lowering DHS's burden for justifying construction projects, as new appropriations might not need to be requested for each project. In contrast, having a secure, readily available source of funds might allow DHS great flexibility and efficiency in planning and executing future construction projects.

Community Concerns

Operation of PIADC has engendered some controversy among nongovernmental organizations and others, who have expressed concerns about the potential for pathogen release, illicit research, and unintended consequences.[109] Local opposition also increased following suggestions by the federal government of upgrading the biocontainment facilities from BSL-3Ag to BSL-4 to allow work on more dangerous pathogens. Those suggestions were not acted upon.[110] Questions regarding worker safety and the potential for human infections by pathogens that affect both humans and animals have also been raised.[111] The DHS, through informational sessions in the EIS process, has attempted to allay these concerns and has stated that community acceptance, or at least minimal community resistance, is one of the NBAF site criteria. However, continued community outreach may be a key factor in determining whether NBAF will suffer delays that have threatened construction of other high-containment laboratories.[112]

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[109] See John Rather, "Heaping More Dirt On Plum I.," *New York Times,* February 15, 2004, and Beth Daley, "Danger Island," *Boston Globe*, September 11, 2001.

[110] John Rather, "East End Germ Lab Getting an Upgrade," *New York Times*, November 25, 2001.

[111] Occupational exposure to dangerous, federally regulated pathogens in a laboratory at Boston University and Texas A&M University are cited as examples of such events. (M. Anita Barry, *Report of Pneumonic Tularemia in Three Boston University Researchers, November 2004 — March 2005*, Boston Public Health Commission, March 28, 2005 and Emily Ramshaw, "CDC Suspends A&M Research on Infectious Diseases; CDC Suspends Bioagent Work after Exposures Not Reported Promptly," *The Dallas Morning News*, July 2, 2007.)

[112] Barbara Goodson, "Judge Hits BU Biolab; Ruling Calls for Safety Review, May Stall Plan," *The Boston Herald,* August 4, 2006.