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2009

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

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

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December 14, 2009

**Congressional Research Service**

7-5700

[www.crs.gov](http://www.crs.gov)

RL34160

**CRS Report for Congress**

*Prepared for Members and Committees of Congress*

## Summary

The agricultural and food infrastructure of the United States may be susceptible to terrorist attack using biological pathogens. In addition to the economic effects of such an attack, some animal pathogens could cause illness in humans. Diseases that can spread from animals to people 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 the introduction of non-native animal disease, Congress has appropriated funds to the U.S. Department of Agriculture (USDA). Some of this work is performed at the Plum Island Animal Disease Center (PIADC), located off the coast of New York. Congress created the Department of Homeland Security (DHS) in 2003 and transferred ownership and operation of PIADC from USDA to DHS. The USDA and DHS cooperate to conduct foreign animal disease research at PIADC, but they have identified PIADC as outdated and too limited to continue as the primary facility for this research.

Homeland Security Presidential Directive 9, issued by President G.W. Bush, 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 appropriate funds to construct a new facility, the National Bio- and Agro-Defense Facility (NBAF). This facility would house high-biocontainment laboratories able to hold the pathogens currently under investigation at PIADC, as well as other pathogens of interest. The DHS has selected Manhattan, Kansas, as the NBAF site and plans to open the facility in 2015. The DHS estimates the final, total facility construction cost as \$725 million, significantly exceeding earlier projections. Additional expenses, such as equipping the new facility, relocating existing personnel and programs, and preparing the PIADC facility for disposition, are expected to add \$190 million.

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.

The DHS plans regarding the NBAF raise several policy issues. 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.

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## Introduction

The U.S. agricultural and food infrastructure is a key component of economic productivity and growth. A terrorist attack on this infrastructure could damage the public's trust in agricultural safety and quality and the nation's ability to provide food and other agricultural products.<sup>1</sup> Additionally, many animal diseases can infect humans.<sup>2</sup> These types of diseases are termed *zoonotic*. Scientific and medical understanding of zoonotic diseases in their animal hosts may lead to the discovery and development of new medical countermeasures for the animals themselves, as well as 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.<sup>3</sup> 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. The DHS asserts that PIADC can no longer continue as the primary facility performing this research.<sup>4</sup>

Homeland Security Presidential Directive 9 (HSPD-9), issued by President G.W. Bush, 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 diagnostic capabilities for foreign animal and zoonotic diseases.”<sup>5</sup> The Secretary of Homeland Security is directed 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.”<sup>6</sup>

The Department of Homeland Security announced it will establish a new facility, the National Bio- and Agro-Defense Facility (NBAF), to meet the obligations of HSPD-9.<sup>7</sup> This facility would

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

<sup>2</sup> Examples include influenza, plague, West Nile fever, and Rift Valley fever.

<sup>3</sup> These diseases are sometimes referred to as foreign animal diseases (FAD).

<sup>4</sup> Department of Homeland Security, Science and Technology Directorate, *FY2006 Congressional Justification*, p. 44.

<sup>5</sup> 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.

<sup>6</sup> *Ibid.*

<sup>7</sup> 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

have high-containment laboratories able to hold the pathogens currently under investigation at PIADC, as well as other pathogens of interest. The DHS engaged in a site-selection process to determine the location for the NBAF. After evaluating several sites, DHS released a draft<sup>8</sup> and a final Environmental Impact Statement (EIS)<sup>9</sup> addressing each site. The DHS chose Manhattan, Kansas, as the NBAF location.<sup>10</sup> The DHS plans to establish NBAF on the mainland have raised congressional and public concerns regarding its safety and security and policy questions regarding DHS and USDA coordination of research to be conducted at NBAF. Additionally, the projected costs for the NBAF have continued to increase.

This report outlines progress towards establishment of the NBAF, presents projected funding requirements and timelines, and analyzes policy issues of potential interest to Congress. These issues include the need for and scope of the laboratory, the possible consequences of a pathogen release, the adequacy of pathogen-release response plans, the sufficiency of plans to conduct highly contagious animal disease research on the mainland, the extent of interagency coordination, the slippage of construction timelines, the final disposition of PIADC and Plum Island, and community safety concerns.

## NBAF Research Goals

The DHS intends the new NBAF to be more than just a replacement facility for PIADC; DHS intends it to exceed PIADC's capacity and capability. The highest level of biocontainment available at PIADC is Biosafety Level 3 Agricultural (BSL-3Ag).<sup>11</sup> Because DHS plans to perform experiments with some pathogens that require a higher level of biocontainment, approximately 10% of NBAF's gross square footage would be BSL-4 laboratories.<sup>12</sup>

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;

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<sup>8</sup> 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](http://www.dhs.gov/xres/labs/gc_1187734676776.shtm).

<sup>9</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Final Environmental Impact Statement*, December 2008, available online at [http://www.dhs.gov/xres/labs/gc\\_1187734676776.shtm](http://www.dhs.gov/xres/labs/gc_1187734676776.shtm).

<sup>10</sup> Department of Homeland Security, Science and Technology Directorate, "Record of Decision for the National Bio and Agro-Defense Facility Environmental Impact Statement," 74 *Fed. Reg.* 3065-3080 (January 16, 2009).

<sup>11</sup> Biosafety, in this context, refers to the recommended protective measures to lower the risk of unintentional infection or pathogen release from the laboratory. The Department of Health and Human Services develops and publishes guidelines establishing best practices for four biosafety levels (Department of Health and Human Services, Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety in Microbiological and Biomedical Laboratories*, 5<sup>th</sup> 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>). For more on biosafety levels and high containment laboratories see CRS Report R40418, *Oversight of High-Containment Biological Laboratories: Issues for Congress*, by Frank Gottron and Dana A. Shea.

<sup>12</sup> For example, Nipah virus research requires BSL-4 biocontainment. 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>.

- 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.<sup>13</sup>

The research agenda for NBAF is to be at least partially based on current risk assessments and subject to change along with assessed risk. 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 encephalitis, Hendra virus disease, contagious bovine pleuropneumonia, and Japanese encephalitis.<sup>14</sup> The DHS plans to perform research at NBAF to study how these pathogens enter the animal, what types of cells 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.

## NBAF Site Selection

In January 2006, DHS issued a Request for Expressions of Interest from consortia interested in hosting NBAF. In August 2006, DHS selected 18 sites from the 29 submitted expressions of interest for further evaluation. An intergovernmental review group, which included DHS, USDA, the Department of Health and Human Services, and the Department of Defense, evaluated these sites.

In July 2007, DHS selected five sites as finalists for further analysis (see **Table 1**). This analysis included preparation of an Environmental Impact Statement (EIS) that evaluated the selected sites. The DHS added Plum Island as a selected site, even though DHS had not responded to its own Request for Expressions of Interest nor evaluated Plum Island during the intergovernmental review. Subsequent to the selection of the final sites, potential irregularities in the selection process were identified.<sup>15</sup> 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.”<sup>16</sup>

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<sup>13</sup> 71 *Fed. Reg.* 3107-3109, January 19, 2006.

<sup>14</sup> 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](http://www.dhs.gov/xres/labs/gc_1181073261627.shtm).

<sup>15</sup> Larry Margasak, “NBAF Choices Suspect; Experts Ignored,” *Associated Press*, August 10, 2008.

<sup>16</sup> *Ibid.*

**Table I. Finalists for NBAF Site**

<b>Consortium</b>	<b>Location</b>
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	Plum Island, NY

**Source:** DHS, online at [http://www.dhs.gov/xres/labs/gc\\_1184180641312.shtm](http://www.dhs.gov/xres/labs/gc_1184180641312.shtm) and 72 *Fed. Reg.* 41764-41765 (July 31, 2007).

The EIS development involved public hearings and comment.<sup>17</sup> The DHS published the draft EIS for comment in June 2008.<sup>18</sup> Following the public comment period, DHS published the final EIS in December 2008.<sup>19</sup>

In January 2009, DHS chose Manhattan, Kansas, as the site for the new facility.<sup>20</sup> According to DHS, it based this decision on the EIS and other completed analyses. Other studies and assessments DHS identified as used included:

- Threat and Risk Assessment,
- Site Cost Analysis,
- Site Characterization Study,
- Plum Island Facility Closure and Transition Cost Study, and
- prior analysis of the alternative sites against DHS's site selection evaluation criteria.<sup>21</sup>

A panel of government employees considered the information in these reports and reported its findings to the DHS Under Secretary for Science and Technology who chose the site.<sup>22</sup> The selection criteria included:

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<sup>17</sup> 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).

<sup>18</sup> 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](http://www.dhs.gov/xres/labs/gc_1187734676776.shtm).

<sup>19</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Final Environmental Impact Statement*, December 2008, available online at [http://www.dhs.gov/xres/labs/gc\\_1187734676776.shtm](http://www.dhs.gov/xres/labs/gc_1187734676776.shtm).

<sup>20</sup> Department of Homeland Security, Science and Technology Directorate, "Record of Decision for the National Bio and Agro-Defense Facility Environmental Impact Statement," 74 *Fed. Reg.* 3065-3080 (January 16, 2009).

<sup>21</sup> 73 *Fed. Reg.* 36541 (June 27, 2008).

<sup>22</sup> Department of Homeland Security, personal communication, August 18, 2008.



- proximity to research capabilities;
- proximity to workforce;
- cost of acquisition, construction, and operations;
- community acceptance;
- relative threat and risk; and
- environmental impacts.

According to DHS's analysis, each proposed site's environmental impact and relative threat and risk were "very similar."<sup>23</sup> Of the remaining four criteria, DHS gave greater consideration of the site's proximity to research facilities that could be linked to NBAF's mission.<sup>24</sup>

## NBAF Funding

In the DHS Science and Technology Directorate 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. The NBAF was to cost \$451 million and begin operation in 2010. Subsequent budget and planning documents have changed both the final cost projections and the date when operations begin (see **Table 2**). The DHS Science and Technology Directorate FY2010 congressional budget justification states that the facility will cost \$915 million. The DHS anticipates completing facility construction in 2015 and commencing full operation of NBAF in 2017.<sup>25</sup> It remains unclear how any additional construction delays would affect the total cost of the project and future annual appropriations requests.<sup>26</sup>

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<sup>23</sup> Department of Homeland Security, *Preferred Alternative Selection Memorandum for the National Bio and Agro-Defense Facility (NBAF)*, December 4, 2008, p. 5, available online at [http://www.dhs.gov/xlibrary/assets/nbaf\\_preferred\\_alternative\\_memo.pdf](http://www.dhs.gov/xlibrary/assets/nbaf_preferred_alternative_memo.pdf).

<sup>24</sup> Department of Homeland Security, Science and Technology Directorate, "Record of Decision for the National Bio and Agro-Defense Facility Environmental Impact Statement," 74 *Fed. Reg.* 3065-3080 (January 16, 2009) at 3071.

<sup>25</sup> Department of Homeland Security, *FY2010 Congressional Justification*, p. S&T R&D 161.

<sup>26</sup> 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.

**Table 2. Changing NBAF Funding Requirements**

(\$ in millions)

Year of Projection	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010	FY2011	Total
2005	3.0	23.0 <sup>a</sup>	73.0	129.0	129.0	94.0	0	451.0
2007	0 <sup>a</sup>	12.0 <sup>a</sup>	23.0	11.0	45.6	184.9	172.0	448.5 <sup>b</sup>
2008	0 <sup>a</sup>	12.0 <sup>a</sup>	23.0 <sup>a</sup>	11.0	35.6	183.8	170.7	436.1 <sup>c</sup>
2009	0 <sup>a</sup>	12.0 <sup>a</sup>	23.0 <sup>a</sup>	11.0 <sup>a</sup>	35.6	96.3	737.1 <sup>d</sup>	915.0 <sup>e</sup>

**Source:** CRS calculations based on data from 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; Department of Homeland Security, personal communication September 10, 2007; Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2008-2012*, August 2008; and Department of Homeland Security, Science and Technology Directorate, *FY2010 Congressional Budget Justification*.

- a. These values 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 predicted construction to continue until 2014.
- c. This projection indicated that DHS would not request any appropriations in FY2012 or FY2013 for NBAF construction.
- d. The DHS combined projected costs for FY2011-FY2014 into a single entry in this projection.
- e. The DHS included site-specific costs in this estimate, which partially accounts for the large increase between 2008 and 2009 projections. See "Site Specific and Additional Costs." This figure includes \$725 million in site-specific costs shown in **Table 3**, and \$190 million for decontamination, deconstruction, and relocation expenses.

## 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 might increase the total cost above \$451 million.<sup>27</sup> Cost projections prior to the January 2009 site selection excluded such site-specific costs. In 2008, DHS published site-specific construction cost estimates (see **Table 3**).<sup>28</sup>

<sup>27</sup> Such site specific costs might include improving electrical, water, or transportation infrastructure for particular sites. 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.

<sup>28</sup> 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](http://www.dhs.gov/xres/labs/gc_1187734676776.shtm).

**Table 3. Site-Specific Cost Estimates**

(\$ in millions)

Cost Category	2005 Baseline	KS	NY
<b>Construction</b>	390.0 <sup>a</sup>	563.0	752.4
<b>Other Costs<sup>b</sup></b>	61.0 <sup>c</sup>	161.6	186.9
<b>Total</b>	<b>451.0</b>	<b>724.6<sup>d</sup></b>	<b>939.3</b>

**Source:** CRS calculations from Department of Homeland Security 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.
- d. Does not include \$190 million in decontamination, deconstruction, and relocation expenses. When these costs are included the total equals \$915 million as indicated in **Table 2**.

The DHS cost analysis shows that the 2005 baseline underestimated the total cost of the project. The total construction cost for the preferred site is \$725 million, \$274 million or 60% higher than the 2005 baseline projection. This cost includes \$173 million more in infrastructure upgrades and other site specific costs and \$100 million more in non-site-specific costs. Some of the increase in other costs reflects additional charges arising from services not originally included in the 2005 baseline.

By choosing a site on the mainland, DHS may be able to offset some of the NBAF construction costs by selling Plum Island (see “Selling Plum Island” below). However, the site will likely require deconstruction, decontamination, and remediation before DHS can sell Plum Island. Additionally, DHS will incur expenses transferring equipment and projects from PIADC to NBAF. The DHS estimates costs for deconstruction, decontamination, remediation, and relocation will total \$190 million.<sup>29</sup> The DHS has projected requesting \$61 million in FY2013 for the initial contract award for PIADC decontamination and decommissioning planning and scoping.<sup>30</sup>

The NBAF construction funding requirements may be lowered by contributions from the Heartland BioAgro Consortium, the supporters of the Kansas site. The DHS expects the consortium to provide land for NBAF at no cost and invest an additional \$110 million in infrastructure upgrades as “in-kind” contributions.<sup>31</sup>

## NBAF Appropriations

Actual NBAF funding did not follow early projections (see **Table 4**). The DHS has requested, and received, appropriations at a level lower than initially projected in 2005. The DHS Science and Technology Directorate FY2006 congressional budget justification stated that NBAF funding

<sup>29</sup> Department of Homeland Security, *FY2010 Congressional Justification*, p. S&T R&D 161.

<sup>30</sup> Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2008-2012*, August 2008, p. 143.

<sup>31</sup> Department of Homeland Security, *FY2010 Congressional Justification*, p. S&T R&D 161.

began in FY2005 when “\$3 M was received for a planning and feasibility study from base funding of Biological Countermeasures.”<sup>32</sup> However, DHS has subsequently clarified that the FY2005 funding was used elsewhere in DHS and that FY2006 and FY2007 appropriations funded these studies.<sup>33</sup> In FY2006, Congress appropriated \$23 million to select a site and conduct other pre-construction activities.<sup>34</sup> In FY2007, an additional \$23 million was appropriated for site selection and other pre-construction activities.<sup>35</sup> 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.<sup>36</sup> In FY2008, Congress appropriated \$11 million to continue environmental studies necessary to select a site for NBAF.<sup>37</sup> In FY2009, Congress fully funded the President’s \$35.6 million request to continue progress on NBAF construction.<sup>38</sup> In FY2010, Congress appropriated \$32 million for NBAF construction and a related National Academy of Sciences study.<sup>39</sup> However, Congress restricted the use of FY2009 and FY2010 appropriations pending additional reviews of the risk assessment process (see “Congressional Restrictions on the Use of Appropriated Funds”).

**Table 4. NBAF Funding**  
(\$ in millions)

Action	FY2005	FY2006	FY2007	FY2008	FY2009	FY2010
DHS Allocation	3	—	—	—	—	—
DHS Reallocation	(3)	—	—	—	—	—
P.L. 109-90	—	23	—	—	—	—
P.L. 109-295	—	(11)	23	—	—	—
P.L. 110-161	—	—	—	11	—	—
P.L. 110-329	—	—	—	—	36	—
P.L. 111-83	—	—	—	—	—	32
<b>Total Annual Appropriations</b>	<b>0</b>	<b>12</b>	<b>23</b>	<b>11</b>	<b>36</b>	<b>32</b>

**Source:** Funding rounded to nearest million. CRS calculations based on DHS congressional budget justifications, H.Rept. 109-241, H.Rept. 109-699, Committee Print of the Committee on Appropriations, U.S. House of Representatives, on H.R. 2638/P.L. 110-329, H.Rept. 111-298, and DHS personal communications.

<sup>32</sup> Department of Homeland Security, Science and Technology Directorate, *FY2006 Congressional Justification*, p. 45.

<sup>33</sup> Department of Homeland Security, personal communication, September 10, 2007.

<sup>34</sup> H.Rept. 109-241 to accompany H.R. 2360 (P.L. 109-90), p. 78.

<sup>35</sup> H.Rept. 109-699 to accompany H.R. 5441 (P.L. 109-295), p. 168.

<sup>36</sup> Department of Homeland Security, personal communication, September 10, 2007.

<sup>37</sup> P.L. 110-161, *Consolidated Appropriations Act, 2008*.

<sup>38</sup> P.L. 110-329, *Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009*.

<sup>39</sup> H.Rept. 111-298.

## Policy Issues

The 110<sup>th</sup> Congress passed NBAF-related legislation to allow DHS to perform live foot-and-mouth disease (FMD) virus research on the mainland and to sell Plum Island. The Food, Conservation, and Energy Act of 2008 (P.L. 110-246, also referred to as the 2008 farm bill) requires the Secretary of Agriculture to provide DHS a permit to possess live FMD virus on the U.S. mainland at a single facility that succeeds PIADC. The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329) requires the sale of Plum Island if DHS selects a mainland site for NBAF.

In addition to the basic funding issues discussed above regarding increasing projected construction costs and the appropriate annual funding level, NBAF raises several other policy issues. These include the need for and scope of the laboratory, the possible consequences of a pathogen release, the adequacy of pathogen-release response plans, the sufficiency of plans to conduct highly contagious animal disease research on the mainland, the extent of interagency coordination, the slippage of construction timelines, the final disposition of PIADC and Plum Island, and community safety concerns.

## Need for and Scope of NBAF

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 congressional mandate,<sup>40</sup> USDA commissioned a strategic planning task force that recommended the “Agricultural Research Service must consider upgrading current Level 2 and Level 3 bio-containment units for animals and constructing a Level 4 unit.”<sup>41</sup> 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.”<sup>42</sup>

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.<sup>43</sup>

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

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<sup>40</sup> P.L. 104-127, Subtitle D, section 884.

<sup>41</sup> U.S. Department of Agriculture, *Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations*, August 1999, p. 24.

<sup>42</sup> National Research Council, *Critical Needs for Research in Veterinary Science*, (National Academies Press: Washington, DC) 2005.

<sup>43</sup> House Committee on Science, *An Overview of the Federal R&D Budget for Fiscal Year 2007*, Committee Serial No. 109-35, February 15, 2006.

The DHS projects the size of NBAF to be more than 500,000 gross square feet.<sup>44</sup> Approximately 55,000 gross square feet of the facility would be BSL-4 laboratory space (see **Table 5**). The NBAF would be more than twice as large as PIADC.<sup>45</sup> This sizeable increase in laboratory capacity may meet the requirements put forth by HSPD-9, as well as establishing the expanded, modern facilities necessary to replace PIADC and perform research activities. Full use of this expanded laboratory space may pose a challenge to federal research planners. Other federal agencies have also expanded their research laboratory capacity, including BSL-3Ag space, providing alternative venues for performing such research.<sup>46</sup>

**Table 5. NBAF Space Compared to PIADC Space**  
(Net Square Footage)

Space	NBAF	PIADC
BSL-2	9,570	4,488
BSL-3E	36,080	28,311
BSL-3Ag	62,144	31,868
BSL-4	15,290	0
Vaccine Production	7,080	0
Other	389,803	169,535
<b>Total</b>	<b>519,967</b>	<b>234,202</b>

**Source:** Department of Homeland Security, Science and Technology Directorate, personal communication, April 27, 2009.

**Note:** “Other” includes office and support space including space for mechanical and air handling needs.

The ability of DHS to effectively use the newly constructed BSL-4 and BSL-3Ag laboratories may require efficient interagency cooperation to identify other agency research activities that could be 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. Additionally, the new capability to perform experiments requiring BSL-4 laboratory space may require either additional research and development funding or diversion of funding streams previously devoted to BSL-2 and BSL-3 experiments. The DHS and USDA may need to analyze their current and future BSL-3 BSL-3Ag and BSL-4 research requirements to effectively and efficiently use NBAF.<sup>47</sup>

<sup>44</sup> 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>.

<sup>45</sup> The PIADC has a combined office/laboratory space of 226,560 square feet, excluding other buildings. U.S. Department of Agriculture, *Report on the Strategic Planning Task Force on USDA Research Facilities: Report and Recommendations*, August 1999.

<sup>46</sup> 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.

<sup>47</sup> For example, the National Science and Technology Council issued a research and development plan addressing government research needs in foreign animal disease. See Subcommittee on Foreign Animal Disease Threats, Committee on Homeland and National Security, National Science and Technology Council, *Protecting Against High Consequence Animal Diseases: Research & Development Plan for 2008-2012*, January 2007.

## Adequacy of Protection Against Pathogen Release

A pathogen release is a potential risk at all high-biocontainment laboratories. Laboratory operators implement biosafety and biosecurity guidelines to reduce the probability that a pathogen might be released from a laboratory.<sup>48</sup> Thus, the likelihood that a pathogen would be accidentally or intentionally released from the laboratory into the surrounding area is generally considered to be low, but not zero.

### Biosafety Guidelines

The HHS and USDA have developed guidelines for the construction, maintenance, and operation of high-biocontainment laboratories. These guidelines aim to protect laboratory workers against occupational exposure to pathogens and to minimize accidental pathogen release. The guidelines also 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 government, academic, and industrial laboratories adhere to these biocontainment protocols as a matter of best practice.<sup>49</sup>

Despite procedural and 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 PIADC.<sup>50</sup> Since 2004, laboratory workers in the United States have been exposed to several pathogens, including those that cause tularemia, Ebola hemorrhagic fever, anthrax, Q fever, and brucellosis.<sup>51</sup> The DHS acknowledges that additional biocontainment failures exist.<sup>52</sup>

### Biosecurity Requirements

Congress, responding to security concerns regarding the potential for terrorist use of pathogens, authorized the creation of the “select agent” regulations.<sup>53</sup> Under these regulations, USDA and HHS identify and list as select agents pathogens and toxins that pose a severe threat to public, animal, or plant health. Agricultural select agents are pathogens and toxins, including FMD virus, that pose a severe threat to animal or plant health.<sup>54</sup> 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 register with and pass a security

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<sup>48</sup> For more information on this subject, see CRS Report R40418, *Oversight of High-Containment Biological Laboratories: Issues for Congress*, by Frank Gottron and Dana A. Shea.

<sup>49</sup> Centers for Disease Control and Prevention and National Institutes of Health, Department of Health and Human Services, *Biosafety in Microbiological and Biomedical Laboratories*, 5<sup>th</sup> Edition, February 2007, online at [http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL\\_5th\\_Edition.pdf](http://www.cdc.gov/OD/ohs/biosfty/bmbl5/BMBL_5th_Edition.pdf).

<sup>50</sup> 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.

<sup>51</sup> Jocelyn Kaiser, “Accidents Spur a Closer Look at Risks at Biodefense Labs,” *Science*, September 28, 2007, p. 1852.

<sup>52</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Environmental Impact Statement*, December 2008, Appendix B.

<sup>53</sup> These select agent regulations are codified at 42 C.F.R. 73, 9 C.F.R. 121, and 7 C.F.R. 331.

<sup>54</sup> The agricultural select agent regulations are codified at 9 C.F.R. 121 and 7 C.F.R. 331.

review by the Department of Justice. The PIADC must conform to the Agricultural Select Agent Program regulations promulgated by USDA, and the NBAF would have to conform, as well.

Even with these guidelines and regulations in place, some critics remain concerned that these protections may be insufficient.<sup>55</sup> Government investigations have found many examples of laboratories not complying with the select agent rules. In a 2006 report, the HHS Inspector General investigated representative universities and state, local, private, or commercial laboratories. Eleven of 15 universities investigated had not fully complied with the select agent regulations. None of the eight state, local, private, or commercial laboratories investigated were in full compliance with the select agent regulations.<sup>56</sup> The USDA Inspector General similarly found compliance problems.<sup>57</sup> The HHS Inspector General levied a total of \$2,037,000 in fines and suspended one laboratory's permission to use select agents in response to these and other violations.<sup>58</sup>

## **Consequences of a Pathogen Release**

Although the likelihood of a pathogen release is low, pathogens have been accidentally released from high containment laboratories. The potential consequences of an accidental or deliberate release vary widely. The impact would depend on many factors, including pathogen type; amount, location, and method of release; weather conditions; nearby presence of susceptible humans or animals; and the effectiveness of any government and private sector response.

The NBAF Environmental Impact Statement addresses some of the consequences of a foreign animal disease pathogen release from NBAF. The EIS analysis focuses mainly on economic consequences rather than on public health. The EIS analysis does not attempt to determine the full range of all possible results from a pathogen release. Neither does it attempt to determine the likely worst-case outcome from a pathogen release. Instead, the EIS analysis relies on a “limited” model to estimate the economic effects of a pathogen release.

The EIS analysis models the release of three of the pathogens (foot-and-mouth-disease virus, Rift Valley fever virus, and Nipah virus) planned to be studied at NBAF.<sup>59</sup> The DHS focused much of its analytic work upon assessing the economic impact from an FMD outbreak. The DHS found that the largest economic factor arose from the expected reduction of trade following an FMD outbreak.

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<sup>55</sup> For example, see testimony by Edward Hammond, Director, The Sunshine Project, before the House Committee on Energy and Commerce, Subcommittee on Oversight and Investigations, October 4, 2007.

<sup>56</sup> 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.

<sup>57</sup> 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.

<sup>58</sup> Total fines as of October 2009. See online at [http://oig.hhs.gov/fraud/enforcement/cmp/agents\\_toxins.asp](http://oig.hhs.gov/fraud/enforcement/cmp/agents_toxins.asp).

<sup>59</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Environmental Impact Statement*, December 2008, p. D-8.



The DHS asserted that an outbreak at any of the proposed sites would have an “equivalent” effect on trade.<sup>60</sup> The DHS identified the economic impact of a FMD outbreak as being in a range between \$2.8 billion (Plum Island) and \$4.2 billion (Manhattan, Kansas). Other studies have identified larger and smaller consequences. In 2008, the USDA developed a complex economic model to estimate the costs associated with outbreaks of foreign animal diseases and determined an FMD outbreak would cost between \$2.8 billion and \$4.1 billion.<sup>61</sup> The correlation between these studies may indicate that the DHS “limited” model provides a sufficient understanding of an FMD outbreak’s economic consequences.

The DHS also considered a release of Rift Valley fever virus, but the EIS does not contain an independent estimate of the economic consequences of an outbreak of Rift Valley fever (RVF). The EIS asserts the costs of an outbreak might “approach the levels projected by the RVF Working Group,” a group of governmental and nongovernmental experts.<sup>62</sup> The RVF Working Group estimated the economic impact of a RVF outbreak at multiple sites as \$50 billion.<sup>63</sup>

Policymakers are faced with a wide range of information regarding the potential for a pathogen release. The DHS asserts that modern biocontainment equipment and approaches will ameliorate the effects of any potential release.<sup>64</sup> The GAO asserts that the risk of a pathogen release may be minimized but not eliminated.<sup>65</sup> The potential economic effects of a disease outbreak may be large or small depending on how the outbreak manifests. Key questions for policymakers are whether they have sufficient information to decide whether the NBAF should be sited on the mainland and whether the potential consequences of a pathogen release are offset by the low likelihood of occurrence and the potential benefits from NBAF construction.

## **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 virus 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 eradication of all potentially infected wildlife.<sup>66</sup> The federal government may be less well prepared to contain other diseases it plans to study at NBAF. In August 2007, the USDA

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<sup>60</sup> Department of Homeland Security, *Preferred Alternative Selection Memorandum for the National Bio and Agro-Defense Facility (NBAF)*, December 4, 2008, p. 5, available online at [http://www.dhs.gov/xlibrary/assets/nbaf\\_preferred\\_alternative\\_memo.pdf](http://www.dhs.gov/xlibrary/assets/nbaf_preferred_alternative_memo.pdf).

<sup>61</sup> Philip Paarlberg, Ann Seitzinger, John Lee, and Kenneth Mathews, Jr., “Economic Impacts of Foreign Animal Disease,” *Economic Research Report Number 57*, May 2008.

<sup>62</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Environmental Impact Statement*, December 2008, p. D-16.

<sup>63</sup> ANSER, *Rift Valley Fever Working Group: Summary Report and Recommendations*, August 24-26, 2004. Available online at [http://nabc.ksu.edu/assets/factsheet\\_docs/rvf/rift%20valley%20report.pdf](http://nabc.ksu.edu/assets/factsheet_docs/rvf/rift%20valley%20report.pdf).

<sup>64</sup> See, for example, oral testimony by John Vitko, 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.

<sup>65</sup> 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.

<sup>66</sup> Bill White, U.S. Department of Agriculture, Public statement at NBAF Draft Environmental Impact Statement Public Meeting, Washington DC, July 24, 2008.

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 U.S. 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.<sup>67</sup>

In subsequent meetings, the Rift Valley Working Group noted that the federal government is making some progress addressing these needs.<sup>68</sup> Although NBAF will not commence research for several years, policymakers might decide that response plans should be fully evaluated and implemented before NBAF begins operations.

## **Should NBAF Be on the Mainland?**

Historically, U.S. researchers have studied highly contagious foreign animal diseases on an island separated from the mainland. This policy arose because of concerns that the disease pathogens might infect animals and spread through domestic wildlife and livestock. Since biocontainment technology has increased in sophistication, DHS has claimed that such research could now be performed safely on the mainland. Additionally, policymakers have questioned the efficacy of a water barrier in preventing animals from swimming to and from an island site and similarly whether air currents could carry pathogens from an island site to the mainland. In the context of NBAF siting and construction, policymakers face a tradeoff between a potentially increased risk of infection following a pathogen release versus lower construction, operation, and maintenance costs, greater operational efficiency, and improved worker 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.”<sup>69</sup> 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.<sup>70</sup> In congressional testimony, DHS stated that modern biocontainment technology is sufficient to prevent an accidental release.<sup>71</sup> However, in the EIS, DHS noted that despite “improved engineering and design of high-

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<sup>67</sup> 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>.

<sup>68</sup> U.S. Department of Agriculture, personal communication, August 18, 2008.

<sup>69</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Environmental Impact Statement*, December 2008, p. 3-446.

<sup>70</sup> Ibid. Table 3.14.4-7, p. 3-446.

<sup>71</sup> See, for example, oral testimony by John Vitko, 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.

biocontainment biological laboratories, accidents due to human error or maintenance failures ... could cause releases,” and described three such incidents since 2006.<sup>72</sup>

Some analysts and foreign governments have concluded that research on certain agricultural pathogens should only be done in geographically isolated laboratories.<sup>73</sup> 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 governments decided to keep the laboratories on islands.<sup>74</sup> 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.<sup>75</sup>

## **Legal Restrictions on Foot and Mouth Disease Virus Research on the Mainland**

Despite the potentially higher costs of a Rift Valley fever virus release, most of the debate about the proposed mainland location of the NBAF has focused on an FMD outbreak. This focus likely arises in part from the existing 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.<sup>76</sup>

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.<sup>77</sup>

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 the Secretary of Agriculture to issue a permit to DHS for live FMD virus research at one successor facility to 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

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<sup>72</sup> Department of Homeland Security, *National Bio and Agro-Defense Facility Environmental Impact Statement*, December 2008, p. 3-373.

<sup>73</sup> Emily Ramshaw, “Texas May Be Home to New Foot-and-mouth Disease Research Lab,” *Dallas Morning News*, November 11, 2007.

<sup>74</sup> 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.

<sup>75</sup> This laboratory’s downtown location may isolate it from susceptible animals. *Ibid.*

<sup>76</sup> Because of concerns about the potential for economic damage from the release of FMD virus into domestic animal stocks, Congress enacted prohibitions in 1948 against performing such 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.

<sup>77</sup> 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.

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.

The DHS and USDA agreed that a permit will be issued to a successor facility to PIADC located on the mainland. According to DHS,

On December 18, 2008, the Secretary of Homeland Security, Michael Chertoff sent a letter to the Secretary of Agriculture, Ed Schafer requesting that a permit be issued if a mainland site is selected. On January 9, 2009, DHS received a letter from Secretary Schafer that affirmed USDA’s intention of complying with Congressional direction to issue a permit for the movement and use of live FMDV at the NBAF.<sup>78</sup>

### **Congressional Restrictions on the Use of Appropriated Funds**

In 2008, GAO concluded that DHS had not performed the necessary analysis to determine whether it is possible to safely perform FMD research on the mainland.<sup>79</sup> Congress, faced with the possibility that DHS had not fully assessed the risks arising from a mainland release of pathogens, directed the Secretary of Homeland Security to complete “a risk assessment of whether foot-and-mouth disease work can be done safely on the United States mainland.”<sup>80</sup> Congress prohibited using FY2009 appropriations for NBAF construction on the mainland until DHS made this assessment and GAO reviewed it. In response, DHS asserted that the risk assessment work done in the EIS met this statutory requirement.

In 2009, GAO was again critical of the risk assessment provided to them. The GAO identified several weaknesses, including the use of a model not designed for pathogen transport; lack of consideration of particular, rather than average, wind strength and direction; and the failure to conservatively consider all parameters. Additionally, GAO found that DHS did not integrate the component assessments performed as parts of the NBAF risk assessment.<sup>81</sup>

Citing GAO’s criticism, Congress prohibited DHS from obligating FY2010 funds for NBAF construction until DHS “undertakes a bio-safety and bio-security mitigation risk assessment ... to determine the requirements for the safe operation of the NBAF in Manhattan, Kansas.”<sup>82</sup> The DHS is directed to use the National Academy of Sciences to obtain an independent evaluation of this study within four months of the study’s completion. The DHS plans to complete its risk assessment before the end of FY2010.<sup>83</sup>

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<sup>78</sup> Department of Homeland Security, Science and Technology Directorate, “Record of Decision for the National Bio and Agro-Defense Facility Environmental Impact Statement,” 74 *Fed. Reg.* 3065-3080 (January 16, 2009) at 3066.

<sup>79</sup> 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.

<sup>80</sup> The Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329).

<sup>81</sup> Government Accountability Office, *Biological Research: Observations on DHS’s Analyses Concerning Whether FMD Research Can Be Done as Safely on the Mainland as on Plum Island*, GAO-09-747, July 30, 2009.

<sup>82</sup> H.Rept. 111-298, p. 120.

<sup>83</sup> Department of Homeland Security, personal communication, December 11, 2009.

## Coordination of Research Activities with Other Agencies

Since NBAF would replace PIADC, policymakers expect USDA and DHS will collaborate on research at NBAF. 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.<sup>84</sup> However, since NBAF also represents an expansion in capacity and capability over PIADC, this relationship may change. Establishment of the new facility provides an opportunity for policymakers to evaluate previous agreements and make adjustments. Assignment of lab space to the Department of Health and Human Services or other agencies may require reevaluation and updates to these procedures.<sup>85</sup>

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.<sup>86</sup> 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 DHS states that it relies on the National Science and Technology Council (NSTC) Foreign Animal Disease Threat Subcommittee to facilitate the overall interagency coordination and to integrate interagency R&D efforts.<sup>87</sup> This subcommittee has issued a research and development strategic plan for government efforts against foreign animal disease.<sup>88</sup> Within DHS, the Joint Agro Defense Office (JADO) provides coordination and staff support for the development and maintenance of an integrated interagency research and development (R&D) strategy for foreign animal disease defense. In FY2009 and FY2010, DHS plans to have JADO assess strategic R&D opportunities at NBAF.<sup>89</sup>

## 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. The DHS must finish construction of NBAF and achieve operational status before down-sizing or decommissioning

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<sup>84</sup> 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.

<sup>85</sup> 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.

<sup>86</sup> 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.

<sup>87</sup> Department of Homeland Security, *FY2010 Congressional Justification*, p. S&T R&D 26.

<sup>88</sup> Subcommittee on Foreign Animal Disease Threats, Committee on Homeland and National Security, National Science and Technology Council, *Protecting Against High Consequence Animal Diseases: Research & Development Plan for 2008-2012*, January 2007.

<sup>89</sup> Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2008-2012*, August 2008.

PIADC if research continuity is to be maintained. Because of the unique research currently performed at PIADC, the smooth transition of this capacity may be an issue of congressional concern. Beyond the 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 DHS and USDA ability to plan for this transition relies on timely NBAF construction.

The original NBAF schedule, as presented to Congress, proposed finishing construction and commissioning NBAF in FY2010. The DHS has extended the proposed schedule several times. In June 2006, DHS estimated NBAF operations would begin in 2013.<sup>90</sup> Until February 2008, the DHS website indicated that operations would begin in 2013 or 2014.<sup>91</sup> In July 2008, DHS estimated NBAF would be completed by January 1, 2015.<sup>92</sup> In 2009, DHS estimated NBAF would be completed in 2015 and become fully operational in 2017.<sup>93</sup>

Each extension of the NBAF construction schedule increases the time that PIADC will be in operation. The PIADC has historically had security, coordination, and other challenges.<sup>94</sup> The DHS has developed and implemented a multi-year *Corrective Action Plan* to address these issues and maintain the operation of PIADC.<sup>95</sup> Extended operation and maintenance of PIADC 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 has not requested additional appropriation for upgrades since FY2008<sup>96</sup> and does not plan to in future years.<sup>97</sup> 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.<sup>98</sup> Further NBAF construction delays may require additional funds be used to support PIADC's corrective maintenance.

## **Selling Plum Island**

The DHS proposed selling Plum Island and using 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, arrange with

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<sup>90</sup> See online at [http://www.dhs.gov/xlibrary/assets/NBAF\\_Timeline.pdf](http://www.dhs.gov/xlibrary/assets/NBAF_Timeline.pdf).

<sup>91</sup> 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](http://www.dhs.gov/xres/labs/gc_1170798884583.shtm).

<sup>92</sup> Department of Homeland Security, *Plum Island Animal Disease Center Facility Closure and Transition Study*, July 2008, p. 12.

<sup>93</sup> Department of Homeland Security, *FY2010 Congressional Justification*, p. S&T R&D 97.

<sup>94</sup> 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.

<sup>95</sup> 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.

<sup>96</sup> Department of Homeland Security, Science and Technology Directorate, *Fiscal Year 2009 Congressional Justification*.

<sup>97</sup> Department of Homeland Security, Science and Technology Directorate, *Five-Year Research and Development Plan, Fiscal Years 2008-2013*, August 2008.

<sup>98</sup> *Ibid.*

the purchaser to allow PIADC 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.<sup>99</sup> Congress endorsed this proposal in the Consolidated Security, Disaster Assistance, and Continuing Appropriations Act, 2009 (P.L. 110-329, signed into law September 30, 2008).

Most sales of surplus property are handled by the General Services Administration (GSA), and any funds received are directed to the Treasury.<sup>100</sup> In contrast, P.L. 110-329 provided authority for DHS to receive the proceeds of the sale of Plum Island. Because the DHS Secretary chose a site other than Plum Island for NBAF, Section 540 requires the Secretary to sell Plum Island through GSA. The proceeds of such a sale

shall 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: Provided further, That after the completion of construction and environmental remediation, the unexpended balances of funds appropriated for costs in the preceding proviso shall be available for transfer to the appropriate account for design and construction of a consolidated Department of Homeland Security Headquarters project, excluding daily operations and maintenance costs, notwithstanding section 503 of this Act, and the Committees on Appropriations of the Senate and the House of Representatives shall be notified 15 days prior to such transfer.

The DHS intends to sell Plum Island in FY2011. The DHS plans to continue operating PIADC and to pay rent to the new owner of Plum Island until NBAF is ready for full operation in FY2017.<sup>101</sup>

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. Additionally, rental payments for the continued operation of PIADC until NBAF completion will reduce the net proceeds of the sale. The sale might provide net funds insufficient for NBAF construction or might provide substantial surplus funds even after NBAF construction is complete.

## Community Concerns

Experience at Plum Island suggests that community concerns could affect a new relocated facility. Operation of PIADC has engendered some controversy among nongovernmental organizations and others. These groups have expressed concerns about the potential for pathogen release, illicit research, and unintended consequences.<sup>102</sup> Local opposition also increased

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<sup>99</sup> Department of Homeland Security, Science and Technology Directorate, *Research, Development, Acquisitions, and Operations, Fiscal Year 2009 Congressional Justification*.

<sup>100</sup> For a brief overview, see CRS Report RS20630, *Disposition of Surplus Federal Property*, by Garrett Hatch.

<sup>101</sup> Department of Homeland Security, *FY2010 Congressional Justification*, p. S&T R&D 97.

<sup>102</sup> See John Rather, “Heaping More Dirt On Plum I.,” *New York Times*, February 15, 2004, and Beth Daley, “Danger (continued...)”

following suggestions by the federal government of upgrading PIADC biocontainment facilities from BSL-3Ag to BSL-4 to allow work on more dangerous pathogens. Those suggestions were not acted upon.<sup>103</sup> Questions regarding worker safety and the potential for human infections by pathogens that affect both humans and animals have also been raised.<sup>104</sup> 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, was 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.<sup>105</sup>

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Island,” *Boston Globe*, September 11, 2001.

<sup>103</sup> John Rather, “East End Germ Lab Getting an Upgrade,” *New York Times*, November 25, 2001.

<sup>104</sup> 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.)

<sup>105</sup> Barbara Goodson, “Judge Hits BU Biolab; Ruling Calls for Safety Review, May Stall Plan,” *The Boston Herald*, August 4, 2006.