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PLUM ISLAND
ANIMAL DISEASE
CENTER

DHS and USDA Are
Successfully
Coordinating Current
Work, but Long-Term
Plans Are Being
Assessed



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Highlights of [GAO-06-132](#), a report to congressional committees

Why GAO Did This Study

The livestock industry, which contributes over \$100 billion annually to the national economy, is vulnerable to foreign animal diseases that, if introduced in the United States, could cause severe economic losses. To protect against such losses, critical research and diagnostic activities are conducted at the Plum Island Animal Disease Center in New York. The Department of Agriculture (USDA) was responsible for Plum Island until June 2003, when provisions of the Homeland Security Act of 2002 transferred the facility to the Department of Homeland Security (DHS). Under an interagency agreement, USDA continues to work on foreign animal diseases at the island. GAO examined (1) DHS and USDA coordination of research and diagnostic activities, (2) changes in research and diagnostic priorities since the transfer, and (3) long-term objectives of joint activities at Plum Island.

What GAO Recommends

To make more effective use of limited space, GAO recommends that DHS, in consultation with USDA, pursue opportunities to shift work that does not require the unique features of Plum Island to other institutions. In commenting on a draft of this report, DHS and USDA generally agreed with the recommendation, but DHS believes it has already addressed it. We believe that more work is needed.

www.gao.gov/cgi-bin/getrpt?GAO-06-132.

To view the full product, including the scope and methodology, click on the link above. For more information, contact Robert A. Robinson at (202) 512-3841 or robinsonr@gao.gov.

PLUM ISLAND ANIMAL DISEASE CENTER

DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed

What GAO Found

DHS and USDA's coordination at Plum Island Animal Disease Center has been largely successful because of the agencies' early efforts to work together to bring structure to their interactions at the island. For example, prior to the transfer, officials from DHS and USDA worked in concert to develop a written interagency agreement—effective when the island was transferred to DHS—that coordinated management activities. Subsequently, DHS and USDA created a detailed strategy to guide their joint work on foreign animal disease research and diagnostics. According to this joint strategy, DHS's role is to augment the research and diagnostic work that USDA's Agricultural Research Service (ARS) and the Animal and Plant Health Inspection Service (APHIS) conduct at the island.

Since the transfer, budget changes, in part, have modified overall priorities and the scope of work at the island. First, ARS narrowed its research priorities to focus its work primarily on a single foreign animal disease, foot-and-mouth disease (FMD). Traditionally one of the high-priority diseases studied at Plum Island, FMD has emerged as its top research priority because, according to officials, it poses the greatest threat of introduction because of its virulence, infectivity, and availability. Other research programs have been terminated or are proceeding at a slower pace. National experts we consulted confirmed the importance of studying FMD, but stated that it is also important to study a variety of other diseases to remain prepared. They suggested that, to free up limited space at the facility, some of the work that does not require the unique features of Plum Island could be performed elsewhere: for example, work that does not involve the use of a live virus, such as certain aspects of vaccine development. Second, while APHIS's overall priorities have not changed, diagnostic work has been curtailed. Officials said that, after the transfer, because the agency did not receive an expected budget increase, their plans to expand development of diagnostic tools for high-priority diseases were curtailed. This work is vital to rapidly identifying diseases when outbreaks occur. APHIS officials told us that the funds to support work on diagnostic tools remain insufficient. Finally, DHS has assumed responsibility for operations and maintenance at Plum Island and has established an applied research science and agricultural forensics team.

While DHS and USDA plan to continue to work together on FMD, agency officials told us that it is not prudent to speculate on long-term objectives at Plum Island, in part, because DHS has plans to replace the Plum Island Animal Disease Center with a new, modernized facility that could be located at Plum Island or elsewhere. Pending congressional approval, DHS estimates that the new facility will be fully operational by 2012.

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Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
DHS	Department of Homeland Security
FMD	foot-and-mouth disease
Joint Strategy	<i>Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs</i>
OMB	Office of Management and Budget
S&T	Science and Technology Directorate
USDA	U.S. Department of Agriculture

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United States Government Accountability Office
Washington, D.C. 20548

December 19, 2005

The Honorable Robert F. Bennett
Chairman
The Honorable Herb Kohl
Ranking Minority Member
Subcommittee on Agriculture, Rural Development,
and Related Agencies
Committee on Appropriations
United States Senate

The Honorable Henry Bonilla
Chairman
The Honorable Rosa DeLauro
Ranking Minority Member
Subcommittee on Agriculture, Rural Development,
Food and Drug Administration, and Related Agencies
Committee on Appropriations
House of Representatives

Over 40 contagious animal diseases identified in other countries—known as foreign animal diseases—threaten the United States’ agriculture economy, the largest and most integrated in the world. A key component of this economy is the livestock industry, which contributes over \$100 billion annually to the gross domestic product. To protect the nation’s animal industries and exports from catastrophic economic losses that would result from the deliberate or accidental introduction of a foreign animal disease, scientists and veterinarians conduct critical research and diagnostic activities at the Plum Island Animal Disease Center, located off the coast of New York.

Plum Island’s research and diagnostic activities stem from its mission to protect U.S. animal industries and exports from deliberate or accidental introductions of foreign animal diseases. The United States is normally free of such diseases, and highly contagious pathogens could cause disastrous losses in the agriculture sector if they were released outside the facility. Plum Island’s activities include conducting research to develop more sensitive and accurate methods of disease detection and identification; developing new strategies to control disease epidemics, including new vaccines and antiviral drugs; investigating suspected cases of foreign animal disease outbreaks in the United States; producing and maintaining materials used in diagnostic tests and vaccines; and training animal health

professionals to recognize and diagnose foreign animal diseases. Moreover, Plum Island is the only facility in the United States that is currently approved to study high-consequence foreign livestock diseases, such as foot-and-mouth disease (FMD), because its laboratory has been equipped with a specially designed biocontainment area that meets specific safety measures.¹ Plum Island's work involves large mammalian animals. In fact, it is the only facility in the United States that has special safety features required to study certain high consequence foreign animal diseases in large animals. Research on other highly pathogenic animal diseases is being conducted at other facilities. For example, highly pathogenic avian influenza is being studied at the U.S. Department of Agriculture's (USDA) Southeast Poultry Research Laboratory in Athens, Georgia, and is being diagnosed at the National Veterinary Services Laboratories in Ames, Iowa.

USDA was responsible for Plum Island until June 1, 2003, when provisions of the Homeland Security Act of 2002 were implemented.² The act transferred Plum Island, including all of its assets and liabilities, to the Department of Homeland Security (DHS). This action shifted overall responsibility for Plum Island to DHS, including all of the costs associated with facility maintenance, operations, and security. The act specified that USDA would continue to have access to Plum Island to conduct diagnostic and research work on foreign animal diseases, and it authorized the President to transfer funds from USDA to DHS to operate Plum Island.³

Responding to concerns from the agriculture sector that the transfer of responsibilities at Plum Island could shift the focus away from agriculture to other DHS priorities, the members of a congressional conference committee inserted language in the conference report accompanying the Consolidated Appropriations Act for fiscal year 2005 requesting that we report on the coordination efforts between DHS and USDA and describe the long-term objectives of joint activities at Plum Island.⁴ In this context, we examined (1) how DHS and USDA coordinate research and diagnostic activities at Plum Island; (2) what changes, if any, have taken place

¹Live FMD virus may be used only at coastal islands such as Plum Island, unless the Secretary of Agriculture specifically authorizes the use of the virus on the U.S. mainland. 21 U.S.C. § 113a.

²Pub. L. No. 107-296, § 310, 116 Stat. 2135, 2174 (2002), codified at 6 U.S.C. § 190.

³6 U.S.C. § 542(b)(3).

⁴H.R. Rep. No. 108-792, p. 666 (2004).

regarding research and diagnostic priorities at Plum Island since the transfer, and the reasons for and implications of such changes; and (3) the long-term objectives of joint DHS and USDA activities at Plum Island.

To address the first and second objectives, we analyzed DHS and USDA strategy documents and interviewed officials at various levels from each agency, including senior leadership officials in Washington, D.C. We also reviewed budget data and interviewed analysts and officials at DHS, USDA, and the Office of Management and Budget (OMB); lead scientists based at Plum Island; and former USDA scientists who left Plum Island after its transfer to DHS. In addition, we reviewed agency budget documents and other budgetary information provided by the agencies to identify changes in funding levels since the transfer and to determine the funding allocations among the programs at Plum Island, before and after the transfer.

We also interviewed selected animal disease experts to respond to the second objective. We selected our experts for their diverse perspectives and technical expertise on animal health and diseases based on the following criteria: (1) recommendations we received from others knowledgeable in the field of foreign animal diseases; (2) area of expertise and experience; and (3) the type of organization represented, including academic institutions and associated research centers.

To address the third objective, we analyzed agency planning documents and interviewed senior leadership officials representing DHS and USDA. Additional details about our scope and methodology are presented in appendix I. We performed our work from March 2005 to December 2005 in accordance with generally accepted government auditing standards.

Results in Brief

Efforts to coordinate work at Plum Island have been largely successful. This success is attributable to DHS and USDA agreeing to work together early on to bring structure to their interactions at the island. For example, an official from USDA's Agricultural Research Service (ARS) told us that prior to the transfer, staff from DHS and USDA worked together to develop a written interagency agreement—effective when the island was transferred—that coordinated management activities. Furthermore, DHS and USDA created a detailed strategy to guide their joint work on the island's two critical functions—conducting research on foreign animal diseases and providing diagnostic services to identify such diseases. According to the strategy, DHS's role is to augment the research and diagnostic work that USDA's ARS and Animal and Plant Health Inspection

Service (APHIS) conduct at the island. For example, DHS's scientists will expand on basic ARS research by advancing efficacy testing and development of vaccines to enhance the nation's ability to respond to a bioterrorism attack. ARS's role at Plum Island continues to involve fundamental research, such as studying the immune response of livestock infected with FMD. APHIS continues to diagnose diseases in livestock and train veterinarians to recognize and diagnose foreign animal diseases. In addition to the joint strategy, DHS and USDA established two other formal mechanisms to ensure that their respective missions are well integrated and to guide routine activities: a Board of Directors and an interagency working group, known as the Senior Leadership Group. The board is composed of top officials from DHS, ARS, and APHIS, and it is responsible for overall management and operations as well as the island's research strategy. The Senior Leadership Group includes one representative from each of the three agencies and addresses immediate on-site management decisions, such as scheduling use of limited laboratory space and shared equipment. Finally, according to the staff we interviewed, frequent informal communication among scientists at the island has contributed to effective coordination.

Program budget changes that occurred soon after the transfer—resulting in part from implementation of the Homeland Security Act of 2002—modified overall priorities and the scope of work at the island.

- First, ARS narrowed its research priorities to focus its work primarily on a single foreign animal disease, FMD. Traditionally one of the high-priority diseases studied at Plum Island, FMD has emerged as the facility's top research priority following the transfer to DHS since, according to officials, it poses the greatest threat of deliberate introduction because of its virulence, infectivity, and availability. Also, ARS responded to budget reductions by slowing research on another high-priority disease—classical swine fever—and by terminating other research programs, such as one for African swine fever. At the same time, ARS negotiated agreements with other organizations, including DHS, under which ARS was reimbursed to carry out mutually beneficial research. The amount of these reimbursements equaled about 80 percent of the total reduction in the ARS program budget that occurred in 2003 after the transfer. Commenting on the new focus of research at Plum Island, most of the nationally recognized animal disease experts we interviewed agreed that it may be prudent to divert limited funds from diseases of lesser importance to the U.S. economy, such as African swine fever, to study FMD. However, all of the experts expressed

concerns that focusing research on a single disease makes livestock more vulnerable to diseases that are not being studied to the same extent or, in some cases, at all. Some of the experts also said that although Plum Island is the only domestic facility where scientists are currently authorized to study live, high-consequence foreign animal disease agents in large animals, some of the research being conducted at the island could be performed elsewhere. Specifically, work that does not involve the use of a live virus, such as certain aspects of vaccine development, does not require the strict biosafety features of Plum Island.

- Second, APHIS's disease diagnostic priorities have not changed, but plans to expand diagnostic services have been curtailed because, according to officials, the agency did not receive an expected budget increase after the transfer. APHIS officials told us that this slowed their plans to expand development of diagnostic tools for high-priority diseases—work that is vital to rapidly identifying diseases when outbreaks occur. However, in fiscal years 2004 and 2005, DHS paid APHIS to perform diagnostic work at Plum Island on DHS's behalf. Despite APHIS not receiving the expected budget increase, the sum of the 2004 DHS reimbursement and the 2004 allocation to the APHIS laboratory at Plum Island are roughly equivalent to the APHIS program budget in the fiscal year before the transfer. APHIS and DHS officials agree that the reimbursements are not an appropriate way to support the agency's diagnostic work. APHIS officials believe that funds to support work on diagnostic tools remain insufficient.
- Third, DHS is now responsible for all of the costs associated with operating and maintaining Plum Island. In addition, the agency continues to implement major infrastructure improvements and is developing its own applied research program. DHS has also used programmatic funds to establish a bioforensics laboratory at Plum Island and plans to use the bioforensics laboratory to validate forensic assays.

Finally, although DHS and USDA officials told us that they plan to continue to work together on FMD, they also said it is not prudent to speculate on the long-term objectives of future joint work at Plum Island, in part, because DHS has plans to replace the existing facility with a new, modernized one at Plum Island or elsewhere. DHS officials believe that this change is necessary because of the shortcomings of the current laboratory facilities at Plum Island, which include insufficient space and an outdated

infrastructure. DHS expects that the new facility will expand its capabilities to protect animal health against terrorist attacks. DHS estimates that, pending congressional approval, the new facility will be fully operational by 2012. DHS officials told us that they have not yet determined the scope of the work to be performed at this new facility, or the facility's size or location—whether Plum Island or elsewhere. They also indicated that they do not yet know whether the new facility would address current research gaps, such as the lack of a higher biosecurity laboratory than Plum Island currently has. Such a laboratory would enable the study of other highly contagious viruses in large animals, such as Nipah virus, which affects swine and can also be fatal to humans. DHS officials emphasized that the dynamic nature of threat assessments makes it difficult to firmly commit to long-term priorities because information and research needs may change depending on the nature of the threat. DHS and USDA officials confirmed that as they explore future work on foreign animal diseases, whether at Plum Island or elsewhere, they will rely on the joint strategy and the mechanisms they have established to implement this strategy to coordinate the effort.

We are making a recommendation aimed at ensuring the effective use of limited space at Plum Island while longer term plans for a new facility are being developed. Specifically, we recommend that DHS, in consultation with USDA, pursue opportunities to shift work that does not require the unique features of Plum Island to other institutions and research centers.

In commenting on a draft of this report, DHS and USDA generally agreed with the report and its recommendation. DHS said that the report accurately reflects the current relationships and coordination between DHS and USDA at Plum Island. While DHS agreed with the recommendation, the agency also believes that it has largely addressed it. While we agree that important and valuable steps have been taken toward implementing the recommendation, we believe additional actions are necessary and have therefore left the recommendation in the report. In particular, we have not seen evidence that DHS is coordinating its assessment, which is still under way, of the laboratory and animal room requirements at Plum Island with USDA.

Background

Plum Island is a federally owned 840-acre island off the northeastern tip of Long Island, New York. Scientists working at the facility are responsible for protecting U.S. livestock against foreign animal diseases that could be accidentally or deliberately introduced into the United States. Animal

health officials define an exotic or foreign animal disease as an important transmissible livestock or poultry disease believed to be absent from the United States and its territories that has the potential to create a significant health or economic impact.

Plum Island's scientists identify the pathogens that cause foreign animal diseases and work to develop vaccines to protect U.S. livestock.⁵ The primary research and diagnostic focus at Plum Island is foreign or exotic diseases that could affect livestock, including cattle, swine, and sheep. In addition to FMD and classical swine fever, other types of livestock diseases that have been studied at Plum Island include African swine fever, rinderpest, and various pox viruses, such as sheep and goat pox. Appendix III provides more extensive information on animal diseases of concern mentioned in this report.

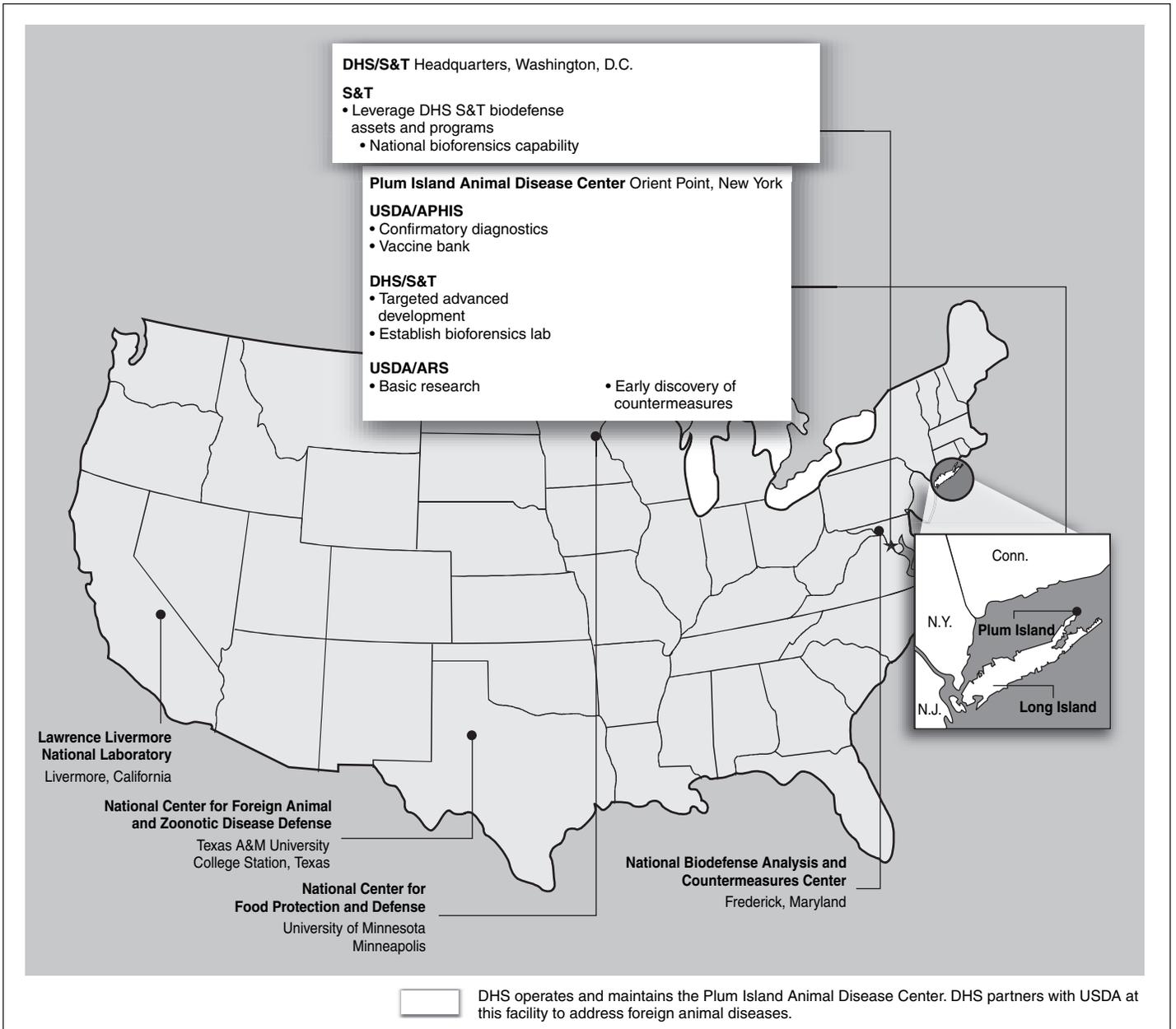
Some of the pathogens maintained at Plum Island are highly contagious; therefore, research on these pathogens is conducted in a biocontainment area that has special safety features designed to contain the pathogens. If accidentally released, these pathogens could cause catastrophic economic losses in the agricultural sector. The biocontainment area includes 40 rooms for livestock and is the only place in the United States that is equipped to permit the study of certain contagious foreign animal diseases in large mammalian animals. USDA uses this biocontainment area for basic research, diagnostic work, and for clinical training of veterinarians in the recognition of foreign animal diseases. These veterinarians would serve as animal health first responders in the event of an emergency. The North American Foot-and-Mouth Disease Vaccine Bank is also located on Plum Island.⁶

⁵USDA conducts research on high-priority diseases affecting animals besides livestock, such as poultry, at other locations. For example, diseases like Newcastle disease and avian influenza, which affect poultry, are studied at USDA's Southeast Poultry Research Laboratory in Athens, Georgia. USDA's National Animal Disease Center in Ames, Iowa, studies indigenous diseases of livestock and poultry, including brucellosis. USDA performs diagnostics on these diseases at the National Veterinary Services Laboratories in Ames, Iowa.

⁶There is no universal FMD vaccine that is effective for all of the subtypes of FMD. The United States stockpiles some FMD vaccines at the North American Foot-and-Mouth Disease Vaccine Bank on Plum Island. However, these vaccines are not stored in a "ready-to-use" state. That is, they are stored as a vaccine antigen concentrate that requires finishing in order to be used.

USDA had owned and operated Plum Island for nearly 50 years when, in June 2003, the island and its assets and liabilities were transferred to DHS. Plum Island is now part of a broader joint strategy developed by DHS and USDA to protect against the intentional or accidental introduction of foreign animal diseases. Under the direction of the DHS's Science and Technology Directorate (S&T), the strategy for protecting livestock also includes work at two of DHS's Centers of Excellence, known as the National Center for Food Protection and Defense and the National Center for Foreign Animal and Zoonotic Disease Defense, as well as other centers within the DHS homeland security biodefense complex. These include the National Biodefense Analysis and Countermeasures Center and the Lawrence Livermore National Laboratory. The strategy calls for building on the strengths of each agency's assets to develop comprehensive preparedness and response capabilities. (See fig. 1.)

Figure 1: The DHS Homeland Security Biodefense Complex



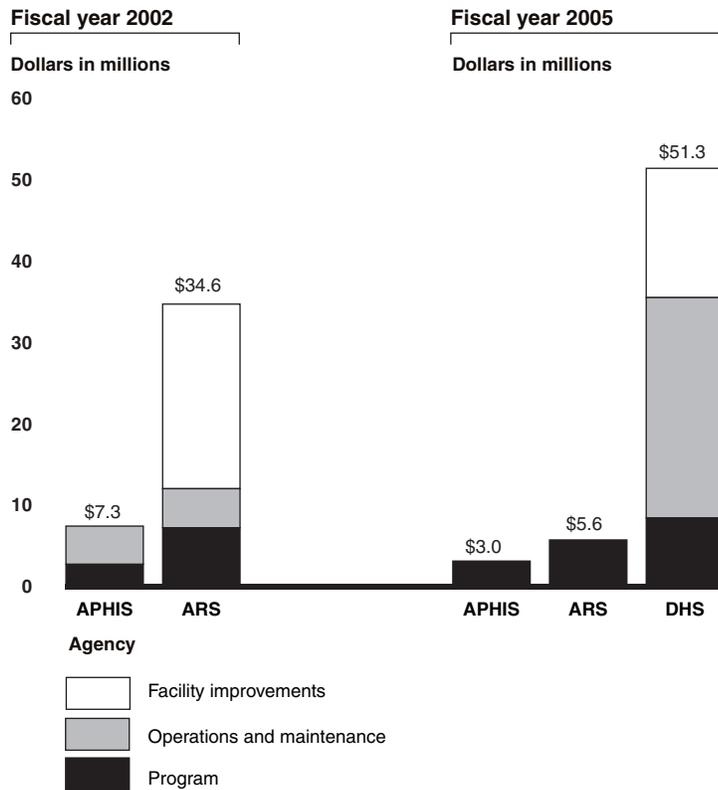
Source: GAO analysis of *A Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs*.

According to the strategy, DHS and USDA now work together to address national biodefense issues and carry out the mission of the Plum Island Animal Disease Center as follows:

- DHS is responsible for coordinating the overall national effort to enhance the protection of agriculture, which the President has defined as a critical infrastructure sector. At Plum Island, DHS's Science and Technology Directorate is working to advance the development of vaccines and disease prophylactics based on ARS's basic research. Also, DHS has established a bioforensics laboratory at Plum Island and is working to conduct forensic analysis of evidence from suspected biocrimes and terrorism involving a foreign animal disease attack.
- USDA/ARS scientists at Plum Island are responsible for basic research on foreign livestock diseases and for early discovery of countermeasures, such as evaluating countermeasures for rapid induction of immunity in livestock.
- USDA/APHIS scientists are responsible for diagnosing livestock diseases. Also, APHIS conducts diagnostic training sessions several times a year to give veterinary health professionals the opportunity to study the clinical signs of animal diseases found in other countries, such as FMD.

Currently, in addition to visiting scientists and fellows, there are approximately 70 federal research scientists, veterinarians, microbiologists, laboratory technicians, and support staff working at Plum Island. DHS and USDA's combined annual operating funds at Plum Island, based on fiscal year 2005 allocations and other funds, is about \$60 million—USDA's funding is about \$8 million, and DHS's is about \$51 million (see fig. 2). Prior to the transfer of Plum Island to DHS, ARS and APHIS shared responsibility for operating costs, although ARS had primary responsibility for the facility. According to agency officials, both agencies received appropriations to execute their research and diagnostic missions, out of which operations and maintenance costs had to be funded. Neither ARS nor APHIS received a specific appropriation for operations and maintenance activities. Now, DHS is responsible for operations and maintenance costs as well as programmatic costs that DHS incurs directly. ARS and APHIS continue to receive funding from USDA to support their own programmatic activities at the island.

Figure 2: Funding Allocations at Plum Island before and after the Transfer



Source: GAO analysis of APHIS, ARS, and DHS data.

Notes: Research funds do not include those allocated to the research consortium for animal vaccines. Congress requires ARS to provide funds directly to participating universities.

The funding amounts listed for ARS and APHIS include funds received from other agencies and entities (including DHS) through reimbursable agreements.

DHS and USDA Have Successfully Coordinated Research and Diagnostic Programs at Plum Island

DHS's and USDA's efforts to coordinate research and diagnostic programs at Plum Island have been largely successful because of the agencies' early efforts to work together to bring structure to their interaction at the island. For example, the agencies developed a joint strategy that outlines how they will pursue their shared mission at Plum Island. They also developed formal mechanisms for coordination, and they rely on frequent informal communication among scientists at Plum Island. The scientists also attribute effective coordination and resolution of transition difficulties to skilled management at Plum Island.

Joint DHS and USDA Strategy Serves as Basis to Prioritize and Coordinate Work

Our review shows a largely positive experience thus far in the coordination of DHS and USDA activities at Plum Island. The success of the agencies resulted from their early efforts to work together to bring structure to their interactions at the island. The agencies developed a framework for coordination in several stages.

- First, in accordance with provisions of the Homeland Security Act of 2002, DHS, ARS, and APHIS worked together before the transfer to establish an interagency agreement. The purpose of the agreement is to establish written guidelines that identify each agency's role and to coordinate immediate operations and maintenance needs, such as fiscal responsibilities and the use of shared equipment. Effective on the day of the transfer, this agreement remained in place while the agencies completed a more detailed strategic plan.⁷
- Second, a working group, composed of DHS, ARS, and APHIS officials, as well as representatives from nongovernmental producer groups, convened about one month after the transfer to review the island's mission and priorities and to develop a strategy for coordination. According to a USDA official, DHS recognized that, as a newly established agency, it needed to seek technical expertise through this interagency group. The group began by discussing foreign animal diseases from a broad perspective to inform the new DHS staff about key issues. Subsequent meetings became more focused as stakeholders evaluated the capabilities of the island and its programs, and identified shortfalls and a common priority for the agencies—FMD. The group finalized a joint strategy to address this priority in August 2004.

The *Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs* (Joint Strategy) serves as the basis for the agencies to prioritize and coordinate work on Plum Island's two critical functions—conducting research on foreign animal diseases and providing diagnostic services to identify such diseases. The Joint Strategy describes the role of each agency at Plum Island; identifies the agencies' common goal to address the threat of foreign animal disease introduction; and outlines the activities that DHS, ARS, and APHIS are to perform to fulfill that goal. In particular, the Joint Strategy identifies gaps in the federal

⁷The interagency agreement is entitled: Interagency Agreement Between the United States Department of Agriculture and the Department of Homeland Security for the Plum Island Animal Disease Center. The agencies review this agreement at least annually.

government's effort to address foreign animal diseases and specifies how DHS programs will fill those gaps. For example, DHS will use its resources and expertise to support efficacy testing and advanced development—an identified gap—of improved vaccines for FMD that showed promising results in the early research stages—i.e., basic research—performed by ARS scientists.

Under the terms of the Joint Strategy, ARS and DHS will conduct research to develop products, such as vaccines, antivirals, and diagnostic tools, that could be used by APHIS, sold on the market, or both. ARS will continue to focus on the early stages of the work and conduct basic research, which explores generally untested ideas. Examples of recent ARS basic research include obtaining new knowledge about diseases and their causative agents and studying the immune responses of livestock infected with FMD. DHS will augment the ARS work by performing targeted applied research, which is intended to lead to the practical use of the most promising basic research results. Among other things, DHS scientists will work with the results from ARS experiments toward developing those concepts into tangible products that will enhance the nation's ability to respond to a bioterrorism attack. For example, ARS scientists could prove a vaccine concept in laboratory experiments, while DHS could conduct the efficacy testing of this vaccine, which would lead to securing licenses required for full-scale manufacture of a vaccine product.

Figure 3: A Laboratory Technician Evaluates Tissue Samples at Plum Island



Source: USDA.

Finally, the Joint Strategy confirms the role of APHIS to conduct confirmatory diagnostic work, develop and validate diagnostic test methods, support the federal and state network of laboratories intended to quickly respond to disease outbreaks, and train veterinarians to recognize and diagnose foreign animal diseases. The Joint Strategy also identifies ways that DHS will augment the diagnostic role of APHIS. DHS will not initiate diagnostic services at the island, but will contribute to APHIS work by supporting validation and deployment of rapid diagnostic technologies and enhancing training capabilities. For example, DHS has modernized educational equipment used by APHIS to teach students and veterinarians about diagnosing foreign animal diseases. DHS has also established its bioforensic laboratory at Plum Island, and DHS scientists will use this laboratory to validate the forensic assays used for FMD.⁸

⁸Diagnostic assays refer to tools used to detect and confirm the presence of disease, whereas forensic assays include those which could be used as evidence in a prosecution. Bioforensics is conducted according to certain protocols such that there is no question about contamination and the analysis can serve as proof in court.

DHS and USDA Rely on Formal and Informal Communication to Coordinate Activities

In addition to the Joint Strategy, the agencies established two other formal mechanisms to ensure that their respective missions are well integrated and to guide routine activities: a Board of Directors and an interagency working group known as the Senior Leadership Group. The agencies also rely on frequent informal communication among scientists and the leadership at Plum Island to further enhance coordination.

Composed of top officials from DHS, ARS, and APHIS, the Board of Directors focuses on overall strategic issues and meets on a quarterly basis. The board includes the DHS Director of the Office of Research and Development, Science and Technology Directorate, and the administrators of both ARS and APHIS. The Director of Plum Island, a DHS employee, participates as the Executive Secretary, but is not a member of the board. The board maintains responsibility for coordination and oversight of all matters relating to the management, administration, research strategy, and operations at Plum Island. The board also ensures that the operation of the facility at Plum Island fulfills the agriculture security mission of the Science and Technology Directorate, ARS, and APHIS.

On the other hand, the Senior Leadership Group provides local management and focuses on immediate on-site management decisions, such as scheduling use of limited laboratory space. The Plum Island-based leaders from each agency make up the Senior Leadership Group, and they meet on at least a monthly basis. The group's responsibilities include (1) establishing operational procedures and practices and conducting strategic planning for future needs, (2) ensuring that individuals who use the facility adhere to its operational procedures and practices, (3) scheduling use of the facility and shared equipment, (4) establishing policies for workers to access the facility, (5) reviewing the compatibility of the work performed at the facility with the island's mission and operations, (6) identifying and coordinating program management for joint projects, and (7) coordinating continuity of operations procedures.⁹

The staff we interviewed at Plum Island also said that frequent informal communication among scientists has contributed to effective coordination. According to the Director of Plum Island, scientists discuss their work with one another on an almost daily basis. One scientist noted that the informal

⁹DHS commented that in the case of limited space, the Senior Leadership Group would, as part of its review of the proposed projects, evaluate whether the work could be done at another location.

dialogue creates a collaborative environment, thereby strengthening their work. The ease of informal communication appears to have resulted in part from existing relationships among the scientists in the three agencies—some of the scientists that now work for DHS at Plum Island previously worked for ARS and APHIS at the island.

In addition, the lead scientists we spoke with attributed the effective integration of DHS at the facility in part to the skilled leadership of the Plum Island Director. For example, several scientists believe that the leader's successful efforts in facilitating open communication among staff have fostered a collaborative environment. Moreover, several noted that the leaders currently based on the island value the comments and ideas expressed by the scientists. One lead scientist concluded that the Director's ability to establish positive relationships with staff has brought greater focus to the research and diagnostic programs. USDA officials also noted that the leadership of the Director and the entire Senior Leadership Group, working as a team, have contributed to effective cooperation at Plum Island.

Finally, while there is now good coordination among the agencies at Plum Island, scientists acknowledged that they experienced some administrative difficulties during the transition period. The scientists we spoke with generally viewed challenges such as these as inevitable given the complexity of transferring responsibility for operations to a new agency and incorporating new programs in the existing facility. For example, one scientist said that the lack of procurement officers initially posed a burden to scientists. He had to perform the duties of a procurement officer—searching for the products, obtaining cost estimates, and completing extensive paperwork—when he needed new supplies and equipment. As a result, this scientist had to forgo some of his limited time in the laboratory and delay his research while he learned how to process procurement orders. This scientist noted, however, that he expected this to be a temporary problem because the agency has since hired administrative staff. DHS officials noted that two procurement officers currently are working at Plum Island, which should alleviate this type of problem in the future.

Budget Changes at Time of the Transfer in Part Modified Overall Priorities and the Scope of Work at Plum Island

Program budget changes that occurred soon after the transfer—resulting in part from implementation of the Homeland Security Act of 2002—modified overall priorities and the scope of USDA’s work at Plum Island. Traditionally one of the high priorities at Plum Island, FMD has emerged as the facility’s top research priority. According to ARS officials, the agency slowed or terminated other research activities in response to the budget reductions that occurred soon after the transfer of the facility to DHS. Many of the experts we spoke with raised concerns about focusing Plum Island’s research resources on one disease. They also noted that some of the aspects of the research being conducted at the island could be performed elsewhere. With regard to the diagnostic component of Plum Island, APHIS’s priorities have not changed, but APHIS officials told us that budget changes at the time of the transfer curtailed the planned expansion of diagnostic services. DHS is now responsible for all of the costs associated with operating and maintaining Plum Island. In addition, DHS continues to implement major infrastructure improvements and is developing its applied research science and agricultural forensics program.

ARS Is Focusing Its Research on FMD, While Other Programs Were Terminated or Slowed Down Because of Budget Reductions

After the transfer, ARS designated FMD—traditionally one of the high-priority diseases at Plum Island—as its top research priority because it poses the greatest threat to the agriculture economy. Also, ARS responded to budget reductions by slowing research on other high-priority diseases, such as classical swine fever, and by terminating research on other diseases, including African swine fever. According to ARS officials, the agency determined the current research priorities—FMD and, to a lesser extent, classical swine fever—using its research plan, which was developed under the agency’s formal planning process, known as the National Program review.¹⁰

In addition to the priorities established by the National Program review, an ARS official told us that the agency also considered other assessments, including those of the White House Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed

¹⁰ARS conducts the National Program review every 5 years to solicit feedback from agriculture stakeholders to identify and establish the research objectives for the ARS program. The review process involves a survey and a series of stakeholder meetings to discuss research objectives. The stakeholders represent knowledgeable officials in academia, industry, and the government. At the time of this report writing—fall of 2005—ARS was preparing to host the 2005 National Program review.

Against Livestock. These assessments consistently ranked African swine fever as a lower threat to the United States than FMD and classical swine fever, and ranked FMD as the top threat to the agriculture economy from a deliberate introduction because of its virulence, infectivity, and availability. African swine fever has been perceived as a less imminent threat to the United States because, according to USDA, outbreaks require a vector, such as a tick, to spread the disease.

As a result of these assessments, as well as a budget reduction soon after the transfer, ARS officials told us that the agency had to slow the pace of some research projects and terminate others. Specifically, ARS terminated the African swine fever research program, which included genomic sequencing of large DNA viruses, and slowed the pace of work on classical swine fever.¹¹ While these officials acknowledged the need to make FMD a research priority at Plum Island, they raised concerns about the effect of budget reductions on other diseases of concern. For example, research on classical swine fever, which included development of a marker vaccine, is proceeding at a slower pace than it did before the budget reductions.¹² An ARS official estimated that the reduced funds for classical swine fever research will extend the project timeline about 5 to 10 years.¹³ Such delays postpone the development of products that would improve the nation's ability to respond to and manage an outbreak of disease.

Since ARS is no longer responsible for operations and maintenance costs at Plum Island, funds to meet these expenses were transferred to DHS in fiscal year 2003. However, a reduction of ARS's programmatic funds for research conducted at Plum Island also occurred. ARS budget data show that the agency's programmatic funds decreased by 45 percent between fiscal years 2003 and 2004. These changes are the result of OMB's actions to

¹¹ARS retained the capacity to sequence viruses in the highest-priority programs, i.e., FMD and classical swine fever. Sequencing enables scientists to better understand the genetic code of viruses and helps to identify and trace the source of diseases. DHS officials noted that the sequencing equipment is used by both agencies.

¹²Once administered to livestock, a marker vaccine elicits a protective immunity that can be distinguished from the immune response elicited by natural infection of the virus. Marker vaccines enable veterinarians to clearly differentiate between animals infected with a disease and those that have been vaccinated. This important distinction would have a significant impact on trade.

¹³USDA has commented that while ARS has had to reduce efforts on classical swine fever due to budget reductions, it has still made significant advances toward the development of a marker vaccine for classical swine fever.

create the first DHS budget for Plum Island in fiscal year 2004. According to an OMB budget examiner, all of the funding for facility operations was transferred to DHS. OMB also divided Plum Island program funds equally between DHS and USDA in fiscal year 2004.

ARS negotiated agreements with other government agencies (including DHS) and a nongovernmental entity under which ARS was reimbursed to carry out mutually beneficial research.¹⁴ The amount of these reimbursements equaled about 80 percent of the reduction in the ARS program budget in 2003 after the transfer. For example, in fiscal years 2004 and 2005, ARS received reimbursements from DHS for research ARS performed in support of DHS's mission. Reimbursements from these agreements, which an ARS official told us are not guaranteed to continue in fiscal year 2006 or beyond, decreased from fiscal year 2004 through 2005. One ARS management analyst noted that the agency cannot factor these reimbursements into program planning because of their inherent uncertainty—such agreements are negotiated as reimbursements on a case-by-case basis after the agency has completed the work.

DHS officials stated that it may appear that ARS's research budget was reduced posttransfer more than it actually was because it is not clear from ARS's fiscal year 2002 and 2003 budgets how much of those budgets included indirect costs (i.e., research overhead costs) and operations and maintenance costs. ARS's budget data for fiscal years 2002 and 2003, however, do not distinguish between indirect costs and operations and maintenance costs. According to an ARS official, DHS now pays for some of the indirect research costs at Plum Island, and the agencies continue to negotiate how to share indirect support costs on a case-by-case basis.

Table 1 summarizes the net effect of the budget reductions and subsequent funding on ARS's research resources, exclusive of building and facility funds, at Plum Island for fiscal years 2002 through 2005.

¹⁴ARS negotiated such agreements with other agencies before the transfer, but total reimbursements under these agreements increased in fiscal year 2004.

Table 1: ARS Plum Island Funding, Fiscal Years 2002-2005

Dollars in millions				
	2002	2003	2004	2005
Total allocated funds^a	\$12.9	\$12.7^b	\$4.3	\$4.8
Operations and maintenance ^c	7.1 ^c	4.4 ^c	0	0
Indirect costs ^c	^c	^c	0.560	0.235
Program funds	5.8	8.3	3.7	4.6
Funds allocated to research consortium ^d	(1.7)	(1.8)	(1.1)	(1.3)
Funds transferred to DHS	^e	(3.2)	^e	^e
Reimbursable interagency agreements and other sources ^f	0.691	0.629	3.7	2.3
Sum of net program funds and reimbursements received	\$4.8	\$3.9	\$6.3	\$5.6

Source: GAO analysis of ARS data.

^aIncludes funding for programmatic activities as well as for operations and maintenance. ARS was not responsible for maintenance and operations costs at the facility after the transfer to DHS. In addition, ARS has spent these funds, which are received from annual appropriations and must be obligated by the end of each fiscal year.

^bAmount that ARS planned, at the start of fiscal year 2003, to allocate to Plum Island. Some of this allocation was then transferred to DHS later that year under the Homeland Security Act of 2002.

^cThe operations and maintenance costs for fiscal years 2002 and 2003 include indirect research costs, which cover support staff and ARS overhead at Plum Island, because the ARS budget did not distinguish between indirect costs and operations and maintenance costs prior to fiscal year 2004.

^dThe House Appropriations Committee directs ARS to provide these funds directly to universities participating in a research consortium.

^eThe direct transfer of funds occurred only in fiscal year 2003. The funds transferred from ARS to DHS in fiscal year 2003 included those used for other facility costs, such as utility and fuel costs, and did not include research dollars.

^fRefers to reimbursements ARS received through agreements with other governmental and nongovernmental entities. In fiscal years 2004 and 2005, these reimbursements include research funds obtained from DHS through Economy Act agreements. Because these funds are from multiyear appropriations, ARS has not completely spent the payments received in fiscal year 2005.

Finally, a senior ARS official expressed concern that because of current funding constraints, research at Plum Island does not address other emerging livestock diseases. This official stated that researching other diseases would mitigate some of the uncertainty and better prepare animal health responders, such as veterinarians, to respond to the unknown. In particular, this official emphasized the importance of developing expertise in other foreign animal diseases.

Experts Regard FMD as the Most Significant Threat but Raised Concerns about Focusing Limited Resources on a Single Disease

Nationally recognized animal disease experts we interviewed agreed that FMD constitutes the greatest threat to American livestock, and, as such, warrants increased attention. Therefore, most of the experts agreed that it is prudent to marshal resources to study FMD at Plum Island. Most of the experts also found it reasonable to terminate research on diseases of lesser importance to the U.S. economy, such as African swine fever. However, all of the experts questioned the wisdom of focusing limited resources almost exclusively on a single disease. Several experts also expressed concern that the focus on a single disease will constrain the development of expertise in other critical diseases, exacerbating the current shortage of talent in this area. For example, one expert told us that there is a shortage of people with an interest in developing expertise in high-priority foreign animal diseases.

In fact, nearly all of the experts we interviewed believed that the current work at Plum Island does not adequately address the potential threats posed by deliberate and accidental introductions of foreign animal diseases other than FMD. Specifically, all but one of the experts we consulted said that focusing research on a single disease makes livestock more vulnerable to the diseases that are not being studied to the same extent, or in some cases, at all, such as Nipah virus. Many of these experts emphasized that because it is difficult to predict foreign animal disease outbreaks, it is important to maintain ongoing research on a range of diseases to be better prepared. As a related example, one scientist pointed out that because little was known about West Nile virus, officials were unprepared when the first outbreak occurred in the United States in 1999. West Nile is a disease that can be fatal to humans, horses, and birds. The first case of West Nile virus in the United States was detected in New York, and the disease spread to an additional 48 states by 2003. An ARS official acknowledged the limitations of focusing research on a single disease and commented that ARS would like to do more research on emerging diseases to be better prepared for the unknown. DHS and ARS officials caution that resource and facility constraints would make it difficult to expand the current research portfolio at Plum Island. Also, such a portfolio would require significantly more stringent biosecurity than is currently in place at the island if research were performed on diseases that could affect both animals and humans.

Some diseases of concern that are not currently being studied at Plum Island include Nipah virus and Rift Valley fever.¹⁵ Members of a blue-ribbon threat assessment panel pinpoint these diseases, which affect both humans and livestock, as warranting greater attention because an outbreak could result in economic disruption or interfere with trade. Some of the experts we interviewed also said that Rift Valley fever research is needed. Research conducted outside of Plum Island on Nipah virus and Rift Valley fever is very limited. At the DHS-funded Center of Excellence at Texas A&M University there are plans to develop a vaccine for Rift Valley fever, but there is limited laboratory space to conduct this type of work on large animals and, therefore, researchers at the center cannot test the vaccine on large animals.¹⁶ The Texas A&M Center of Excellence anticipates that it will rely on institutions overseas, such as the Onderstepoort laboratories in South Africa, to conduct such tests.

DHS and USDA officials told us that in order to study Rift Valley fever on large animals at Plum Island, individuals involved with the research would require a vaccination. Alternatively, Plum Island would need to enhance its biosafety procedures to comply with the stricter biosafety level 4 standards.¹⁷ A DHS official noted that at the time of the transfer of Plum Island, the Homeland Security Secretary pledged to the nearby communities that DHS would not seek a more stringent biosafety designation for the facility.

¹⁵Nipah virus affects pigs, horses, cats, and dogs, and spreads readily from pigs to humans with serious effects. Nipah virus causes serious, and sometimes fatal, encephalitis in humans, and respiratory and central nervous system disease in swine and other animals. Rift Valley fever affects primarily livestock, but also causes illness in humans. Exposure to the Rift Valley fever virus may result in no symptoms or mild illness, such as fever, or more serious illnesses such as hemorrhagic fever, encephalitis, and vision problems.

¹⁶DHS officials told us that funds are being allocated to the development of a vaccine for Rift Valley fever in fiscal year 2006. According to DHS, Plum Island staff will direct the work, but it will not be conducted at Plum Island.

¹⁷Laboratories adhere to specific biosafety guidelines according to their designated biosafety level, which can range from 1 to 4. Biosafety level 1 is acceptable for low-risk organisms that may be found, for example, in high school laboratories. Biosafety level 4 is reserved for a number of exotic and highly lethal pathogens, such as Ebola virus. There are only five facilities in the United States with biosafety level 4 laboratories, including the Department of the Defense's U.S. Army Medical Research Institute of Infectious Diseases and the Department of Health and Human Services' National Institutes of Health. Plum Island operates a biosafety level 3 agriculture laboratory with some additional special agricultural safety features to prevent the release of animal disease pathogens into the environment.

Other experts commented on other factors that limit research on foreign animal diseases. For example, one expert commented that while Plum Island plays a critical role in the national effort to address foreign animal diseases, researchers at this facility cannot study every foreign animal disease of concern, especially given the resource constraints and that the staff do not have expertise in other diseases, such as vector-borne diseases. This expert believes that collaborations between Plum Island and other research institutions would benefit the United States by enhancing the nation's knowledge in areas that researchers would otherwise not be able to address at Plum Island. Several experts suggested that DHS and USDA might use the Plum Island facility more effectively by limiting its research agenda to live infectious agents that can be studied only there and allowing other institutions to perform the work that does not require the stringent safety features of Plum Island. For example, researchers in other institutions could develop vaccines without using a live form of infectious agents or model disease outbreaks. One expert told us that researchers could answer questions through modeling and risk assessment that would be based on the data generated from tests using animals at Plum Island.

Another way to maximize space resources at Plum Island may be to shift work on domestic animal diseases off the island. An expert we consulted said that doing this work at Plum Island decreases the island's already limited resources available to study foreign animal diseases. For example, this expert regards vesicular stomatitis—a disease often mistaken for FMD—as inappropriate for Plum Island because it is a domestic disease and is not highly contagious. Other experts highlighted the value of studying this disease—in part to provide researchers or responders with experience in distinguishing this domestic disease from FMD—but some noted that it might be more appropriate to study it in other laboratories in the mainland United States. USDA commented that it is necessary for the agency to conduct its research on vesicular stomatitis at Plum Island because scientists are working with samples that may be contaminated with FMD. In addition, USDA commented that another benefit from maintaining research on vesicular stomatitis at Plum Island is that such work enables the agency to retain staff trained to work with diseases that affect humans and animals. DHS officials stated that, in their opinion, this type of work constitutes a minimal percentage of Plum Island's workload; a senior ARS official concurred and estimated that this work accounts for roughly 5 percent of the ARS research funds at Plum Island.

According to DHS, the agency is exploring opportunities to involve other research institutions. For example, the DHS officials noted that recently

Plum Island officials have begun to assess what work could be moved off the island to other research facilities while taking into consideration what parts of the combined research tasks can be possibly conducted off of the island.¹⁸ A DHS official told us that the agency has tapped Lawrence Livermore National Laboratory to coordinate closely with Plum Island researchers and develop diagnostic and detection tools for FMD, and demonstrate the performance of such tools in the field. Also, a researcher at the DHS Center of Excellence at Texas A&M stated that the center is investigating genetic methods for preventing FMD, deferring portions of the research requiring use of the live virus to Plum Island; there, a smaller team can handle the virus in a laboratory setting that meets the stringent safety standards. Finally, USDA commented that ARS has established collaborative relationships with eight universities and two other institutions to accomplish its research mission.

APHIS's Priorities Remain the Same, but Budget Changes Curtailed the Planned Expansion of Diagnostic Services

According to APHIS officials, before the transfer of Plum Island to DHS, they expected to receive a \$2.3 million increase in funding, which Congress had approved in February 2003 as part of the agency's appropriations. APHIS was expecting this increased funding to meet rising demand for diagnostic services. Specifically, the 2001 FMD outbreak in the United Kingdom and the emphasis on bioterrorism prompted a shift from passive foreign animal disease surveillance to a more active approach. These events underscored the need for additional staff. In addition, APHIS had assumed responsibility for establishing the validity of rapid diagnostic tools to be used by scientists in a national network of state veterinary laboratories.¹⁹

¹⁸DHS officials told us that discussions regarding coordination of research and maximization of space resources have occurred at the Board of Directors meetings. According to ARS, however, program officials have held such discussions, but not at the level of the Board of Directors.

¹⁹DHS officials recently noted that while APHIS will validate rapid diagnostic tools for foreign animal diseases, DHS is coordinating the field validation of multiplexed diagnostic assays that include domestic diseases that can be confused with FMD.

However, APHIS officials told us that as a result of the transfer, the \$2.3 million increase that APHIS officials were expecting to receive was not fully realized.²⁰ According to budget documents, APHIS had expected to allocate a total of \$4.3 million in fiscal year 2004 to diagnostic work at Plum Island, which included the \$2.3 million. Instead, half of this amount—\$2.1 million—was allocated to the DHS budget for Plum Island that year. OMB decided to use the APHIS fiscal year 2003 budget allocation—which included the \$2.3 million—as a base to determine how much money APHIS and DHS should receive in fiscal year 2004.²¹ Additionally, OMB transferred a portion of APHIS’s fiscal year 2003 programmatic funds (about \$332,000) to cover DHS’s new responsibility for operations and maintenance at Plum Island. This change in fiscal year 2003 funding for APHIS occurred because the Homeland Security Act authorized the President to establish initial funding for DHS by transferring funds from other agencies.²² Although APHIS officials understood that APHIS’s budget for Plum Island would decrease when operations and maintenance funds were allocated to DHS, they did not expect this further reduction in programmatic funds.

APHIS officials noted that although they remain committed to the same diagnostic priorities at Plum Island, the transfer to DHS has strained their diagnostic capabilities at Plum Island. They said their plans to hire more scientists and train more veterinarians to recognize foreign animal diseases were seriously curtailed because they did not receive the anticipated increase. The officials told us that anticipated enhancements to the diagnostic tools at Plum Island would have facilitated a faster response to an outbreak. In fact, an APHIS official told us that, at current funding levels, APHIS staff are able to focus only on validating tests for the highest-priority diseases, such as FMD, and that APHIS lacks the staff and resources to develop tests for other high-priority diseases, such as Rift Valley fever and other emerging diseases. APHIS officials concluded that Plum Island, which is the only place in the United States where hands-on training on high-priority foreign animal diseases affecting livestock can be provided, lacks the capacity to accommodate the increased demand for

²⁰Congress does not appropriate funds directly to the Plum Island facility, but appropriates a lump sum to APHIS. APHIS in turn allocates funds to its programs. An APHIS official told us they based the disbursement on the allocation guidelines recommended in congressional conference reports.

²¹Over and above funds for facility maintenance and operations, according to OMB officials, OMB divided program funds equally between DHS and APHIS.

²²Pub. L. No. 107-296, § 1502, 116 Stat. 2135, 2308 (2002), codified at 6 U.S.C. § 542.

such training. DHS officials noted that, since assuming responsibility for Plum Island, the agency has funded a pilot program to provide distance learning via audiovisual equipment. While the distance training does not provide students with the desirable hands-on experience of observing and diagnosing foreign animal diseases, DHS stated that this tool has augmented the capability of the Foreign Animal Disease Diagnostician Course by providing instruction to practitioners in locations beyond Plum Island.

Figure 4: Veterinarians Participate in Training on Foreign Animal Diseases at Plum Island



Source: USDA.

Though APHIS funding was reduced after the transfer, DHS has reimbursed APHIS to perform diagnostic work at Plum Island in fiscal years 2004 and 2005.²³ For example, in fiscal year 2004, DHS and APHIS negotiated an Economy Act agreement that enabled APHIS to retain eight new scientists—a key step in carrying out its planned expansion of diagnostic services. This agreement covered salary and benefits for eight new APHIS employees rather than ongoing APHIS program costs at Plum Island. The sum of the 2004 DHS reimbursement and the 2004 allocation to the APHIS laboratory at Plum Island are roughly equivalent to the APHIS program budget in the fiscal year before the transfer. However, APHIS officials do not view these reimbursements—referred to as Economy Act agreements—as an appropriate way to fund the agency’s diagnostic work. These officials said that the purpose of the agreements was “to avoid duplicating functions” performed by the agencies at Plum Island, such as caring for the animals, and noted that they do not expect to negotiate additional agreements directly related to the planned expansion. Because the reimbursements obtained through Economy Act agreements have decreased in 2005 and recent congressional appropriations have not been sufficient to support the additional eight scientists, APHIS officials expressed concern about the agency’s ability to retain these scientists. DHS officials concurred with APHIS’s view that Economy Act agreements are not an appropriate way to fund the agency’s diagnostic work at Plum Island.

Table 2 summarizes the net effect of the budget reductions and subsequent funding received through interagency agreements on APHIS’s overall resources at Plum Island for fiscal years 2002 through 2005.

²³DHS and USDA negotiated several reimbursements through Economy Act agreements in fiscal years 2004 and 2005. The Economy Act of 1932 (31 U.S.C. 1535, as amended) authorizes federal agencies to order goods and services from other federal agencies when funds are available, it is in the best interest of the government, and the goods and services cannot be provided as conveniently and cheaply by private industry. The Economy Act generally requires reimbursement for goods and services provided to another agency.

Table 2: APHIS Plum Island Funding, Fiscal Years 2002-2005

Dollars in millions				
	2002	2003	2004	2005
Total allocated funds^a	\$5.9	\$7.1	\$1.7	\$2.5
Operations and maintenance	4.7	4.9	0	0
Program funds	1.1	2.2	1.7	2.5 ^b
Department of Defense supplemental funds ^c	1.45 ^c	1.0 ^c	^c	^c
Funds transferred to DHS	^d	(0.332)	^d	^d
Reimbursable interagency agreements	^e	^e	1.7 ^f	0.473
Sum of net program funds and reimbursements received	\$2.7	\$2.9	\$3.4	\$3.0

Source: GAO analysis of APHIS data.

^aIncludes funding for programmatic activities as well as for operations and maintenance. APHIS was not responsible for maintenance and operations costs at the facility after the transfer to DHS.

^bAccording to USDA, the fiscal year 2005 program funds increased only because the agency redirected funds from other facilities within the National Veterinary Services Laboratories to Plum Island.

^cThe fiscal year 2002 Department of Defense supplemental funding was directed to APHIS at Plum Island. Of the total (\$2.45 million), \$450,000 was used for classical swine fever testing in fiscal year 2002. The remaining portion had to be used for the FMD vaccine bank (\$1 million in fiscal year 2002 and \$1 million in fiscal year 2003; these funds were not available for fiscal years 2004 and 2005).

^dThe direct transfer of funds occurred only in fiscal year 2003.

^eRefers to the payments APHIS received from DHS through Economy Act agreements.

^fUSDA officials understood the payments received in fiscal year 2004 were a partial replacement for funds not received and were intended to cover salaries for APHIS staff at Plum Island.

DHS Continues to Address Infrastructure Needs and Develop Programs Addressing Its Bioterrorism Priorities at Plum Island

As discussed elsewhere in this report, DHS has assumed responsibility for operations and maintenance at Plum Island and has developed its own applied research program. As part of the 2003 transfer authorized by the President, DHS received approximately \$33 million for building and facility funds from ARS and APHIS. In addition to the routine operations and maintenance needs at the facility, the DHS budget at Plum Island includes funds that allow the agency to conduct major infrastructure improvements at the facility. External assessments of the Plum Island facility as well as the agency's own evaluation revealed safety and security issues that the agency needed to resolve. DHS's budget included \$5.9 million in fiscal year 2004 and \$12.9 million in fiscal year 2005 to conduct these improvements at the facility, such as the installation of closed-circuit television surveillance to control and monitor access to the containment area in the laboratory.

DHS officials told us that the security and safety upgrades at Plum Island have increased the funding needs to operate the facility.

The programmatic funds for DHS—which support the agency’s applied research science and agricultural forensics work—accounted for \$8.3 million of the \$51 million total allocated to the agency for Plum Island in fiscal year 2005. As of August 2005, DHS’s applied research science team—which focuses primarily on developing vaccines for FMD—included seven scientists and support staff. DHS has also used its programmatic funds to establish a bioforensics laboratory at Plum Island, which will, according to the agency, validate forensic assays for FMD as well as classical swine fever.

DHS and USDA Are in the Process of Assessing Long-Term Plans for Joint Work at Plum Island

DHS and USDA officials will continue to pursue their current agreed-upon joint activities, which focus on FMD, and they are assessing longer-term objectives for future joint work at Plum Island or elsewhere. Agency officials did not consider it prudent to speculate on long-term objectives of joint work, in part, because DHS plans to replace the existing Plum Island facility, and aspects of the new facility have not yet been determined.

Although DHS and USDA officials told us they plan to continue to work together on FMD, they are currently assessing the longer-term objectives of future joint work at Plum Island or elsewhere. DHS and USDA have established FMD as the immediate top priority for Plum Island, but they have not yet identified which diseases, if any, they will address together after FMD. In fact, the Joint Strategy provides a blueprint for coordinating efforts to address FMD but does not currently address work on other diseases.²⁴ DHS officials told us that the agency remains committed to studying the highest-priority livestock diseases at Plum Island and will decide which diseases to study based on a scientific assessment of the highest threats. DHS and USDA officials confirmed that if they decide to conduct joint activities on other diseases, they will rely on the Joint Strategy and the mechanisms they established to implement this strategy—such as the Board of Directors—to coordinate the effort.

DHS officials emphasized that the dynamic nature of threat assessments makes it difficult to firmly commit to long-term priorities because

²⁴DHS officials noted that the Joint Strategy is being modified.

information and research needs may change frequently depending on the nature of the threat. In terms of USDA research priorities, ARS will establish its research objectives for the next 5 years at the 2005 National Program review and assessment. An ARS official told us that in the near term, the agency would like to conduct more work on classical swine fever, though not at the expense of FMD research. This official noted that no decisions have been made as to whether DHS will coordinate with ARS to address classical swine fever, and that the work on this disease has not yet advanced to a stage that would involve DHS and its applied research capabilities.

Several of the experts we interviewed agreed that, currently, the prioritization of foreign animal disease threats produces the same ranking of diseases whether the threat is based on an accidental or a deliberate introduction; therefore, the experts stated that the current focus on FMD addresses the disease posing the greatest threat through both accidental and intentional introduction. However, the rise of new threats may disrupt the alignment of the agencies' priorities and, in turn, affect the possibility of joint activities. For example, one top ARS official told us that the agencies' research and diagnostic priorities at Plum Island may not continue to be so closely aligned in the future because, in his view, the agencies have different missions. DHS officials noted that the agencies' missions are, in fact, closely aligned because DHS is also responsible for protecting against the accidental introduction of foreign diseases. They also noted that the agency's ranking of diseases would follow a formal risk analysis to prioritize foreign animal diseases based on threat. Based on our analysis of documents such as the Joint Strategy for Plum Island, we believe that DHS's mission to protect agriculture is more oriented toward intentional attacks on agriculture, and, therefore, we expect the agency will continue to focus more on diseases that could be introduced deliberately than on diseases that could accidentally break out in the United States.

Furthermore, officials told us it is premature to firmly commit to long-term objectives of joint work at Plum Island, in part, because DHS has plans to replace the existing facility with a new, modernized facility. Recognizing the shortcomings of the laboratory facilities at Plum Island—insufficient space and outdated infrastructure—a senior DHS official told us the agency will construct this facility, pending congressional approval, to expand its capabilities to defend the nation's agricultural infrastructure against terrorist attacks. DHS officials told us, however, that they have not yet determined the scope of the work to be performed at this new facility, or the facility's size or location—whether Plum Island or elsewhere—and do

not know the extent to which the new facility will carry out the current mission of Plum Island. For example, DHS officials told us the agency has not determined whether the new facility will address such research gaps as the lack of an approved laboratory to study highly contagious viruses like Nipah virus, which require higher biosecurity standards than those in place at Plum Island.

Some DHS and USDA officials speculated that the existing ARS and APHIS programs at Plum Island would move with the DHS applied research program to the new facility, but regardless of the facility's location, the agencies are considering their options. DHS has convened a scientific working group, including representatives from DHS, ARS, APHIS, and the Department of Health and Human Services, to discuss the options for a new facility. DHS estimates that, pending congressional approval, it will become fully operational by 2012.

Conclusions

Although quite successful in terms of interagency cooperation, the transfer of Plum Island from USDA to DHS highlights the challenges that the agencies face in meeting diagnostic and research needs with available resources. The limits on funding and on the availability of laboratory space at Plum Island underscore the importance of leveraging available resources and expertise elsewhere in the country. While Plum Island is the only facility in the United States where scientists are currently authorized to study diseases using certain highly contagious pathogens in large animals, other important work related to these diseases could be conducted in other institutions. As DHS evaluates the size and capabilities of the new foreign animal disease facility that the agency estimates will be completed by 2012, it will be important to explore the cost-effectiveness of shifting some current work, such as research that does not involve the use of live agents, to other laboratories and reserve the limited laboratory space at Plum Island for work that can only be performed in that facility.

Recommendation for Executive Action

To make more effective use of Plum Island's limited laboratory space in the short term, we recommend that DHS's Science and Technology Directorate, in consultation with USDA's Agricultural Research Service and the Animal and Plant Health Inspection Service, pursue opportunities to shift work that does not require the unique features of Plum Island to other institutions and research centers.

Agency Comments

We provided a draft of this report to DHS and USDA for their review and comment.

DHS generally concurred with the report and said that it accurately reflects the current relationships and coordination between DHS and USDA at Plum Island. DHS also agreed with the recommendation and said the agencies have already addressed the issue. For example, DHS commented that the agency's assessment—currently under way—of laboratory and animal room requirements at Plum Island includes addressing the agencies' options for shifting work to institutions off of the island. While we view the steps DHS has taken toward implementing the recommendation as positive, the agency has not completed these tasks. We believe that DHS needs to consult with USDA and conduct more work to demonstrate consideration of opportunities to shift work elsewhere. DHS also provided technical comments, which we incorporated, as appropriate. DHS's written comments and our detailed response appear in appendix IV.

USDA generally agreed with the recommendation and found the report to be factual and generally positive in recognizing the coordination of activities between DHS and USDA. USDA commented that it would continue to evaluate the working relationship with DHS. USDA also provided some clarifying points. For example, USDA noted that while ARS had to reduce efforts on classical swine fever because of budget reductions, it has made significant advances toward the development of a marker vaccine for classical swine fever. USDA also elaborated on our discussion of vesicular stomatitis virus research, and clarified the benefits of conducting such work at Plum Island. Finally, USDA stated that while the recommendation is sound and supported by the agency, the recommendation could be misleading because little of the work can be performed elsewhere and it would be difficult to transfer such work. We have incorporated the clarifications, as appropriate. We also note that although work done at Plum Island that does not require containment may not be easily removed or relocated, it is an important step to take in order to use the facility's limited resources effectively and to be prepared to respond to outbreaks of various foreign animal diseases. USDA also provided technical comments, which we incorporated, as appropriate. USDA's written comments and our detailed response appear in appendix V.

We are sending copies of this report to the appropriate congressional committees, the Secretaries of Homeland Security and Agriculture, and other interested parties. We will also make copies available to others upon request. In addition, the report will be available at no charge on the GAO Web site at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact me at (202) 512-3841 or robinsonr@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.



Robert A. Robinson
Managing Director, Natural Resources
and Environment

Scope and Methodology

To determine how the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA) coordinate research and diagnostic activities at Plum Island, we analyzed DHS and USDA joint strategy documents, including an interagency agreement between DHS and USDA for Plum Island, the *Joint DHS and USDA Strategy for Foreign Animal Disease Research and Diagnostic Programs*, and the Plum Island Animal Disease Center Charter. In addition, we reviewed Homeland Security Presidential Directives 9 and 10 to understand the roles for DHS and USDA in addressing the threat of agricultural terrorism. We interviewed officials at various levels from each agency, including senior leadership officials based in Washington, D.C., the facility's on-site leadership, and, during a visit to Plum Island, all of the lead scientists. We also interviewed former USDA scientists who have left Plum Island since its transfer to DHS on June 1, 2003.

To determine what changes, if any, have taken place regarding research and diagnostic priorities at Plum Island since the facility was transferred to DHS, and the reasons for and implications of such changes, we interviewed the current and two former Plum Island directors, spoke with current and former Plum Island scientists, and discussed research and diagnostic priorities with senior officials in the DHS Science and Technology Directorate and USDA's Agricultural Research Service (ARS) and Animal and Plant Health and Inspection Service (APHIS). To understand Plum Island's budget, we also interviewed analysts and officials at the agencies and at the White House Office of Management and Budget, which developed and oversaw the DHS budget during the creation of the agency. In addition, we analyzed agency budget documents for fiscal years 2002 through 2006 to identify changes in funding levels before and after the transfer of Plum Island and to determine the funding allocations among the programs at Plum Island.

We also conducted structured interviews in person or via telephone with recognized nongovernment experts from academic and other research organizations that we chose for their diverse perspectives and technical expertise on animal health and diseases.¹ In particular, we sought to obtain their comments on research and diagnostic priorities at Plum Island. We based our initial selection of experts on a list of stakeholders invited to

¹In addition, we spoke with a USDA APHIS attache as well as the chief executive officer of a science consulting company that specializes in threat reduction and disease surveillance and response systems.

participate in the ARS's National Program Review Workshop, which met on September 20-21, 2005, in Kansas City, Missouri, to provide feedback on ARS priorities and national research programs. From the list of workshop participants, we identified 13 stakeholders who do not work at Plum Island and who study foreign animal diseases or serve as members in organizations that address foreign animal diseases. This list included some recognized experts who have served on reputable committees assessing the threats of animal diseases, including the White House Office of Science and Technology Policy Blue Ribbon Panel on the Threat of Biological Terrorism Directed Against Livestock. We identified an additional two contacts through referrals from these stakeholders. From these 15 contacts, we selected the final 11 experts on the basis of the following criteria: (1) recommendations we received from others knowledgeable in the field of foreign animal diseases; (2) area of expertise and experience; and (3) type of organization represented, including academic institutions and associated research centers.

To examine the long-term objectives of joint activities at Plum Island, we analyzed agency planning documents and interviewed senior leadership officials representing DHS and USDA. We also discussed with DHS and USDA officials the status and possible outcomes of a DHS feasibility study to upgrade the Plum Island Animal Disease Center.

We conducted our review from March 2005 to December 2005 in accordance with generally accepted government auditing standards.

List of Experts Interviewed

- Roger Breeze, Ph.D., M.R.C.V.S. Chief Executive Officer, Centaur Science Group, Washington, D.C. Former Director, Plum Island Animal Disease Center.¹
- Corrie Brown, Ph.D., D.V.M. Professor and Coordinator of International Activities, Department of Veterinary Medicine, University of Georgia, Athens, Georgia.²
- Neville Clarke, Ph.D., D.V.M. Director, National Center for Foreign Animal and Zoonotic Disease Defense, College Station, Texas.
- Peter Cowen, Ph.D., D.V.M., M.P.V.M. Associate Professor of Epidemiology and Public Health, Department of Population Health and Pathobiology, College of Veterinary Medicine, North Carolina State University, Raleigh, North Carolina.
- Linda L. Logan, Ph.D., D.V.M. USDA APHIS Attache serving North Africa, East Africa, the Middle East and the Near East, Cairo, Egypt.³
- Peter W. Mason, Ph.D. Professor of Pathology, Professor of Microbiology and Immunology; Senior Scientist, Sealy Center for Vaccine Development; member, Center for Biodefense and Emerging Infectious Diseases, University of Texas Medical Branch, Galveston, Texas.
- James A. Roth, Ph.D., D.V.M. Distinguished Professor of Immunology; Assistant Dean, International Programs and Public Policy; and Director, Center for Food Security and Public Health, College of Veterinary Medicine, Iowa State University, Ames, Iowa.

¹M.R.C.V.S. is a member of the Royal College of Veterinary Surgeons. Ph.D. is a doctorate of philosophy degree.

²D.V.M. is a doctorate of veterinary medicine degree.

³Dr. Logan did not speak on behalf of USDA, but answered GAO's questions based on her professional expertise.

Appendix II
List of Experts Interviewed

- M.D. Salman, Ph.D., M.P.V.M., D.A.C.V.P.M., F.A.C.E. Professor and Director of Animal Population Health Institute, College of Veterinary Medicine and Biomedical Sciences, Colorado State University, Fort Collins, Colorado.⁴
- Mark C. Thurmond, Ph.D., D.V.M. Professor, Department of Medicine and Epidemiology, University of California, Davis, California.
- Alfonso Torres, Ph.D., D.V.M. Executive Director, New York State Animal Health Diagnostic Laboratory, and Associate Dean for Veterinary Public Policy, College of Veterinary Medicine, Cornell University, Ithaca, New York.
- David H. Zeman, Ph.D., D.V.M. Department Head, Veterinary Science Department; Director, Animal Disease Research and Diagnostic Laboratory; and Director, Olson Biochemistry Laboratories, South Dakota State University, Brookings, South Dakota.

We also sought the perspective of agricultural producers:

- Gary Weber, Ph.D. Executive Director, Regulatory Affairs, National Cattlemen's Beef Association, Washington, D.C.; and
- National Pork Board.⁵

⁴M.P.V.M. is a master of preventive veterinary medicine. D.A.C.V.P.M. is a diplomat, American College of Veterinary Preventive Medicine. F.A.C.E. is a fellow, American College of Epidemiology.

⁵While we attempted to contact representatives at the National Pork Board several times, we did not receive responses to our questions.

Animal Diseases That Affect Livestock

The table below presents information about key aspects of animal diseases that can affect livestock mentioned in the report, including the animals affected, transmission route, and vaccine ability.

Diseases and agents	Animals affected	Route of transmission	Distribution	Availability of vaccine	Can affect humans
African swine fever	Domestic and wild pigs, wart hogs	Direct contact with body fluids, especially blood; fomites; tick vectors	Africa	No	No
Brucellosis	Main threat to cattle, bison, and swine	Direct contact	Worldwide	Yes	Yes
Classical swine fever	Domestic pigs	Ingestion (uncooked garbage); fomites; aerosol; direct contact	Africa, Asia, Europe, South America	Yes	No
Foot-and-mouth disease	All cloven hoofed animals, including cattle, sheep, goats, pigs	Aerosol; direct contact; ingestion; fomites	Africa, Asia, Middle East, South America	Yes	Yes, but rarely infects humans
Nipah virus	Pigs, horses, cats, dogs	Close direct contact with contaminated tissue or body fluids	Southeast Asia	No	Yes
Rift Valley fever	Cattle, sheep, goats, dogs, cats, camels, monkeys	Insect vectors (mosquitoes); direct contact with blood or tissue	Africa	Yes	Yes
Rinderpest	Cattle, sheep, goats	Direct or close contact with body fluids	Indian subcontinent, Near East, sub-Sahara	Yes	No
Sheep and goat pox	Sheep, goats	Aerosol; direct contact, fomites, mechanically by arthropods	Africa, Asia, Middle East	Yes	No
Vesicular stomatitis	Horses, donkeys, mules, cattle, pigs	Insect vectors, direct contact, fomites, aerosol	North and Central America, Northern part of South America	Yes	Yes
West Nile virus	Birds, many mammals, reptiles	Mosquito vectors	Africa, Asia, Europe, Middle East, North America	Yes (for prevention in horses)	Yes

Source: GAO.

Comments from the Department of Homeland Security

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

U.S. Department of Homeland Security
Washington, DC 20528



**Homeland
Security**

November 22, 2005

Mr. Robert A. Robinson
Managing Director
Natural Resources and Environment
U.S. Government Accountability Office
441 G Street, NW
Washington, DC 20548

Dear Mr. Robinson:

Thank you for the opportunity to comment on draft report GAO-06-132, *Plum Island Animal Disease Center: DHS and USDA Are Successfully Coordinating Current Work, but Long-Term Plans Are Being Assessed*. Technical comments have been provided under separate cover.

Overall, the report accurately reflects the current relationships and coordination that have been established between the Department of Homeland Security's (DHS's) and the United States Department of Agriculture's (USDA's) personnel and programs at the Plum Island Animal Disease Center (PIADC). DHS agrees with the recommendation to make maximum use of the limited laboratory space by conducting work on the Island that uniquely needs to be accomplished on the Island.

There are several references to the scope of the DHS research program for vaccines being limited to foot and mouth disease. It should be noted that in FY2006, DHS funds are also being allocated to Rift Valley fever vaccine development. This work will be directed by staff at Plum Island but will not be conducted at Plum Island.

In reference to the report's analysis that "our mission to protect agriculture is more oriented toward intentional attacks on agriculture" and that we will not be looking at diseases that could accidentally break out, we would like to point out that the Department's mission includes, as stated in the Homeland Security Presidential Directive/HSPD9 *Defense of United States Agriculture and Food*, that DHS is responsible for "coordinating the overall national effort to enhance the protection of critical infrastructure and key resources of the United States." In such a role, it is important for DHS not only to enhance protection against intentional attacks but also against major disease outbreaks that could severely impact agriculture infrastructure, the food supply or the economy. This risk-based approach to all high consequence threats allows DHS to focus on those areas that are most critical.

www.dhs.gov

See comment 1.

See comment 2.

Appendix IV
Comments from the Department of Homeland
Security

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See comment 3.

With regard to the report's recommendation to pursue opportunities to shift work that does not require the stringent biosafety features of Plum Island to other institutions and research centers, DHS and USDA have already worked to address this issue. At the very first PIADC Board of Directors meeting in December 2004, the attendees discussed determining how best to safely ensure both maximum flexibility and a timely decision making process. In response to this discussion, USDA's Animal and Plant Health Inspection Service (APHIS) revised the charter of its Emergency Management Leadership Team (EMLT) to include this capability within its duties. The EMLT meets regularly and will be able to rapidly process requests from any of the agencies at Plum Island or other research groups.

See comment 4.

In addition, the Senior Leadership Group (SLG) at PIADC has instituted an animal room reservation system that allows the SLG to review proposed projects and ensure the best use of the current rooms. In case of limitations on space, part of this review would include an analysis as to whether the work could be done in another location.

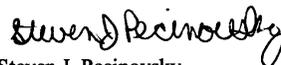
See comment 5.

DHS also has underway an assessment of laboratory and animal room requirements for USDA's Agricultural Research Service, APHIS and DHS for the next six years (2006-2011) on a project basis. Part of this assessment includes addressing each organization's options for performance off-island through other facilities, contract research organizations, other countries, etc.

Consequently, we believe this recommendation for executive action has already been addressed and request that it not be included in the final report as we consider this issue closed.

Thank you again for the opportunity to comment on this draft report and we look forward to working with you on future homeland security issues.

Sincerely,



Steven J. Pecinovsky
Director
Departmental GAO/OIG Liaison Office

The following are GAO's comments on the Department of Homeland Security's letter dated November 22, 2005.

GAO Comments

1. Regarding DHS's comment that the scope of its research program is not limited to FMD, our report notes that the DHS-funded Center of Excellence has plans to develop a vaccine for Rift Valley fever. In addition, we have modified the report to include a statement that DHS funds are being allocated to the development of a vaccine for Rift Valley fever in fiscal year 2006.
2. Regarding DHS's assertion that its mission includes enhancing protection against major disease outbreaks, our report states that DHS's mission to protect agriculture includes responsibilities to address introductions of high consequence foreign animal diseases that could be either deliberately or accidentally introduced. However, we continue to believe that DHS's mission to protect agriculture is more oriented toward intentional attacks on agriculture. First, the Homeland Security Act of 2002 states that DHS's primary mission is to prevent terrorist attacks within the United States.¹ Second, the information DHS provided about its role at Plum Island has emphasized deliberate introductions. For example, the Joint Strategy emphasizes the bioterrorism focus of DHS work at Plum Island in describing the agency's mission "to conduct, stimulate, and enable research and development to prevent or mitigate the effects of catastrophic terrorism." The Joint Strategy also states that DHS will "focus on identified research and development gaps specifically targeted to strengthen the nation's ability to anticipate, prevent, respond to, and recover from the intentional introduction of a high consequence foreign animal disease."
3. Although DHS said that the Board of Directors meetings included a discussion of what work could be conducted off the island, USDA officials disagree with this statement. Furthermore, while we understand that the Board of Directors has met on several occasions, we do not have evidence to support that a discussion about maximizing space resources occurred at the meeting. We also have not seen an outcome of discussions regarding shifting work to other institutions.

¹Pub. L. No. 107-296, § 101(b), 116 Stat. 2135, 2142 (2002), codified at 6 U.S.C. § 111(b).

4. Regarding DHS's comment that the Senior Leadership Group has instituted a room reservation system that takes into consideration work that can be shifted elsewhere, our report states that the Senior Leadership Group has implemented a system to ensure efficient use of limited space at Plum Island. We have modified the report to note that in the case of limited space, the Senior Leadership Group would, as part of its review of the proposed projects, evaluate whether the work could be done at another location. However, as our report states, space is already limited at Plum Island, constraining research and diagnostic work that can be performed at the facility. We have not seen evidence that this group has formally evaluated the feasibility of shifting work from Plum Island to other research institutions in order to overcome resource constraints.

5. We are encouraged to hear that DHS is in the process of assessing the laboratory and animal room requirements for all three agencies at Plum Island for the next 6 years and, as part of this assessment, will address each agency's options for performing activities off of the island through other facilities, contract research organizations, and the like. However, because the assessment has not been completed yet, and we have not seen evidence that DHS is conducting this review in conjunction with USDA, we continue to believe that the agencies have not identified opportunities to shift work that does not require the unique features of Plum Island to other institutions and research centers.

Comments from the U.S. Department of Agriculture

Note: GAO comments supplementing those in the report text appear at the end of this appendix.



United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

NOV 30 2005

IN REPLY

REFER TO: Draft Report GAO-06-132, "Plum Island Animal Disease Center: DHS and USDA are Successfully Coordinating Current Work, but Long-Term Plans are Being Assessed" (360562)

Mr. Robert A. Robinson
Managing Director
Natural Resources and Environment
United States Government Accountability Office
Washington, D.C. 20548

Dear Mr. Robinson:

On behalf of Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS), we thank you for the opportunity to review and comment on the subject draft report. We are providing general comments for your use in preparing the final report and have submitted technical comments under separate cover.

We sense the report to be factual and generally positive in recognizing the coordination of activities between the Department of Homeland Security (DHS) and the Department of Agriculture (USDA). Overall, we generally agree with the recommendations in the draft report, and will continue to evaluate the working relationship with DHS and implement appropriate recommendations and measures of this report as our resources permit.

We would like to take this opportunity to clarify a few points:

- While ARS has had to reduce efforts on Classical Swine Fever due to budget reductions, it has made significant advances toward the development of a marker vaccine for Classical Swine Fever and continues a significant emphasis on Classical Swine Fever research.
- The Vesicular Stomatitis Virus (VSV) research that ARS is carrying out involves strains from countries such as Brazil, Colombia, Ecuador, Peru, etc. which have Foot and Mouth Disease (FMD). Because of the latter research on these VSV strains must be carried out at the Plum Island Animal Disease Center (PIADC). The report should also mention that maintaining research on

See comment 1.

See comment 2.

Mr. Robert A. Robinson

2

VSV provides the capability of maintaining staff that are trained in working with a zoonotic disease.

- If a zoonotic virus were to emerge, it is important to have staff that are comfortable wearing respirators and other personal protective equipment and accustomed to following strict BSL-3 procedures.
- The impact on the nation's preparedness following the transfer of programmatic funds from APHIS and ARS to DHS for a related but distinct area of work is reflected in the report but not in the conclusions. The loss of diagnostic detection and response capability and research capacity will need to be replaced.
- The recommendation to shift work that does not require the stringent biosafety features of Plum Island to other institutions and research centers while being sound and supported by USDA is misleading. Very little of what is being done on the Island (in the containment facility) is work that could be done elsewhere. The "non-BSL-3" work that is being done in the labs and animal rooms fits so tightly into the research/diagnostic programs that it could not be easily removed and relocated.
- The report makes several references to "modeling." USDA is not currently carrying out any modeling activities in the containment facility. Modeling and the use of killed, engineered, or surrogate agents off the island is supported by USDA in those situations where the assurance of biosafety and reliable results is justified. In addition, currently ARS has formal collaborative relationships with eight universities and two other institutions in accomplishing its research mission. As an example, most of the tools used today to evaluate immune response to FMD vaccines were developed at PIADC in collaboration with a University of Missouri scientist currently at the University of Texas Medical Branch.
- While concern has been raised about the Department's decision to prioritize research on foot-and-mouth disease (FMD), it must be emphasized that FMD is the most economically important single livestock disease worldwide and perhaps the most contagious. Concern was also raised about the availability of funds for diagnostic work. The Department constantly balances multiple needs and takes into consideration many priorities when preparing its annual budget.

See comment 3.

See comment 4.

See comment 5.

See comment 6.

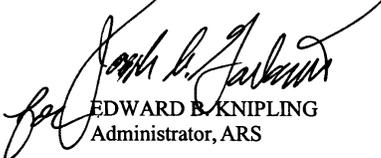
Appendix V
Comments from the U.S. Department of
Agriculture

Mr. Robert A. Robinson

3

Once again, we appreciate the chance to provide our review and comment on this draft report.

Sincerely,


EDWARD B. KNIPLING
Administrator, ARS


for W. RON DEHAVEN
Administrator, APHIS



Office of the Administrator
1400 Independence Avenue, SW
Washington, DC 20250-0300
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The following are GAO's comments on the U.S. Department of Agriculture's letter dated November 30, 2005.

GAO Comments

1. Regarding USDA's comments about ARS's continued focus on classical swine fever and its advances in developing a marker vaccine for this disease, our report notes that this disease is a high priority. We modified the report to include USDA's view that while ARS has had to reduce efforts on classical swine fever due to budget reductions, it has made significant advances toward the development of a marker vaccine for classical swine fever.
2. Regarding USDA's comments about the value of working on vesicular stomatitis virus at Plum Island, our report summarizes the conflicting views of experts regarding the need for such work at Plum Island. We have modified the report to summarize why USDA believes it is important to maintain research on vesicular stomatitis virus at Plum Island.
3. Regarding USDA's comment on the transfer of programmatic funds from ARS and APHIS to DHS for a related but distinct area of work, our report states that after the transfer, there have been increased demands for the facility's limited space and resources related to research and diagnostic activities. Our conclusions summarize the challenges the agencies face in meeting research and diagnostic needs with available resources, and form the basis of our recommendation that DHS's Science and Technology Directorate work with USDA's ARS and APHIS to pursue opportunities to make more effective use of Plum Island's limited laboratory space.
4. Regarding USDA's comments on the recommendation to pursue opportunities to shift work that does not require the unique features of Plum Island to other institutions and research centers, we recognize that not all such work may be relocated or easily removed. For example, as our report notes, any work involving a live FMD agent would have to be conducted at Plum Island. Furthermore, the report states that Plum Island is the only facility that has special safety features required to study certain high consequence foreign animal diseases in large animals. However, we continue to believe that there are opportunities to shift work to other institutions. For example, experts identified work that could be done outside of Plum Island, such as developing vaccines without using the live form of the agents. This

work is important in order to remain prepared to respond to outbreaks of various foreign animal diseases.

5. Regarding USDA's comment on modeling, we modified our report to clarify that modeling activity does not occur in containment.

GAO Contact and Staff Acknowledgments

GAO Contact

Robert A. Robinson, (202) 512-3841 or robinsonr@gao.gov

Staff Acknowledgments

In addition to the contact named above, Maria Cristina Gobin (Assistant Director), Kate Cardamone, Nancy Crothers, Mary Denigan-Macauley, Lynn Musser, Omari Norman, Joshua Smith, and Lisa Vojta made key contributions to this report. Sharon Caudle, Elizabeth Curda, Denise Fantone, Terry Horner, Katherine Raheb, Keith Rhodes, and Steve Rossman also made important contributions.

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