



July 2020

# NATIONAL BIO AND AGRO-DEFENSE FACILITY

DHS and USDA Are  
Working to Transfer  
Ownership and  
Prepare for  
Operations, but  
Critical Steps Remain

# GAO Highlights

Highlights of [GAO-20-331](#), a report to congressional committees

## Why GAO Did This Study

Foreign animal diseases—some of which infect people—can pose threats to the United States. USDA and DHS have been developing NBAF to conduct research on and develop countermeasures (e.g., vaccines) for such diseases, as part of a national policy to defend U.S. agriculture against terrorist attacks and other emergencies. DHS is constructing NBAF in Manhattan, Kansas.

DHS originally assumed responsibility for owning and operating NBAF. However, USDA will carry out this responsibility instead, following an executive order from 2017 to improve efficiency of government programs. Construction is expected to cost about \$1.25 billion.

GAO was asked to review issues related to development of NBAF and USDA's plans for operating it. This report examines (1) efforts to transfer ownership of NBAF from DHS to USDA and to prepare for the facility's operation and (2) USDA's efforts to collaborate with stakeholders.

GAO reviewed DHS and USDA documents and interviewed key department officials and various stakeholders. GAO also compared the departments' efforts on NBAF with selected key practices for government reforms and collaboration.

View [GAO-20-331](#). For more information, contact Steve D. Morris at (202) 512-3841 or [morris@gao.gov](mailto:morris@gao.gov).

July 2020

## NATIONAL BIO AND AGRO-DEFENSE FACILITY

### DHS and USDA Are Working to Transfer Ownership and Prepare for Operations, but Critical Steps Remain

## What GAO Found

The Department of Homeland Security (DHS) and U.S. Department of Agriculture (USDA) have taken steps to plan for and implement the successful transfer of the National Bio and Agro-Defense Facility (NBAF) from DHS to USDA for ownership and operation. (See figure.) The facility is to house state-of-the-art laboratories for research on foreign animal diseases—diseases not known to be present in the United States—that could infect U.S. livestock and, in some cases, people. The departments' steps are consistent with selected key practices for implementation of government reforms. In addition, USDA has taken steps to prepare for NBAF's operation by identifying and addressing staffing needs; these steps are consistent with other selected key practices GAO examined for strategically managing the federal workforce during a government reorganization.

However, critical steps remain to implement the transfer of ownership of NBAF to USDA and prepare for the facility's operation, and some efforts have been delayed. Critical steps include obtaining approvals to work with high-consequence pathogens such as foot-and-mouth disease, and physically transferring pathogens to the facility. DHS estimates that construction of NBAF has been delayed by at least 2.5 months because of the effects of the COVID-19 pandemic. USDA officials stated that, until the full effects of delays to construction are known, USDA cannot fully assess the effects on its efforts to prepare for the facility's operation. In addition, USDA's planning efforts were delayed before the pandemic for the Biologics Development Module—a laboratory at NBAF intended to enhance and expedite the transition of vaccines and other countermeasures from research to commercial viability. A November 2018 schedule called for USDA to develop the business model and operating plan for the module in 2019. Officials stated in May 2020 that USDA intends to develop the business model and operating plan by fiscal year 2020's end.

#### Construction Site of the National Bio and Agro-Defense Facility (NBAF) as of November 2019 and an Artist's Rendering of NBAF When Complete



Source: Department of Homeland Security and NBAF Design Partnership. | GAO-20-331

USDA's efforts to date to collaborate with DHS and other key federal or industry stakeholders on NBAF have included

- meeting regularly with DHS officials to define mission and research priorities,
- developing written agreements with DHS about DHS's roles and responsibilities before and after the transfer, and
- collaborating with the intelligence community, as well as with relevant international research groups and global alliances, on an ongoing basis.

These efforts are consistent with selected key practices for interagency collaboration, such as including relevant participants and clarifying roles.

United States Government Accountability Office

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## Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
BSL	Biological safety level
COVID-19	Coronavirus Disease 2019
DHS	Department of Homeland Security
DHS S&T	Department of Homeland Security Science & Technology
HSPD-9	Homeland Security Policy Directive-9
IT	Information technology
NBACC	National Biodefense Analysis and Countermeasures Center
NBAF	National Bio and Agro-Defense Facility
Plum Island	Plum Island Animal Disease Center
Select Agent Program	Federal Select Agent Program
USDA	U.S. Department of Agriculture

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July 10, 2020

The Honorable Pat Roberts  
Chairman  
The Honorable Debbie Stabenow  
Ranking Member  
Committee on Agriculture, Nutrition, and Forestry  
United States Senate

The Honorable Ron Johnson  
Chairman  
The Honorable Gary Peters  
Ranking Member  
Committee on Homeland Security and Governmental Affairs  
United States Senate

Emerging zoonotic diseases—infectious diseases that can be transmitted between animals and humans—can have potentially serious impacts for human health, animal health, the economy, and trade. For example, Rift Valley fever most commonly affects cloven-hoofed animals but can be transmitted to humans, potentially causing severe symptoms such as inflammation of the brain, hemorrhagic fever, and, in a few cases, death.<sup>1</sup> In addition, Coronavirus Disease 2019 (COVID-19), a global pandemic, is believed to have originated in animals, according to the Centers for Disease Control and Prevention (CDC).<sup>2</sup> Major factors driving the emergence of zoonotic diseases include global travel, trade in exotic animals, agricultural expansion, urbanization, habitat destruction, and an increasing demand for animal protein. These factors may also pose a risk

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<sup>1</sup>Centers for Disease Control and Prevention, *Rift Valley Fever Fact Sheet*, accessed April 3, 2020, <https://www.cdc.gov/vhf/rvf/RVF-FactSheet.pdf>. According to CDC, Rift Valley fever is an acute, fever-causing virus most commonly observed in domesticated animals (such as cattle, buffalo, sheep, goats, and camels). People can be infected with the virus through contact with blood, body fluids, or tissues of infected animals, mainly livestock. Less commonly, people can be infected with the virus from bites of infected mosquitoes and, rarely, from other biting insects. Spread from person to person has not been documented.

<sup>2</sup>Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Situation Summary*, accessed May 3, 2020, <https://www.cdc.gov/coronavirus/2019-NCOV/cases-updates/summary.html#emergence>. Early on, many of the patients at the epicenter of the outbreak in Wuhan, Hubei Province, China, had some link to a large animal market, suggesting animal-to-person spread, according to CDC.

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that foreign animal diseases—diseases not known to exist in the United States—could infect U.S. livestock.

Even when such diseases do not pose a risk to human health, their consequences can be severe. For example, as we have previously reported, a U.S. outbreak of foot-and-mouth disease, a highly contagious foreign animal disease that affects cloven-hoofed animals, could cause billions of dollars in economic losses and could also affect the nation's food supply since the disease makes it difficult for animals to stand or eat, thus greatly reducing production of meat or milk.<sup>3</sup> Also, an outbreak of African swine fever, which has recently spread through China and other countries, would have a significant impact on U.S. livestock producers, their communities, and the economy if it were found in the United States.

To help defend against the threat of zoonotic diseases, among other threats, in January 2004, the President issued Homeland Security Policy Directive-9 (HSPD-9), which established a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies.<sup>4</sup> For example, HSPD-9 tasks the U.S. Department of Agriculture (USDA) and the Department of Homeland Security (DHS) with developing a plan to provide safe, secure, and state-of-the-art laboratories for research on and development of diagnostic capabilities and countermeasures for zoonotic and foreign animal diseases (which can include zoonotic diseases). In response to this directive, the agencies have been developing a new facility—known as the National Bio and Agro-Defense Facility (NBAF)—intended to replace the aging Plum Island Animal Disease Center (Plum Island).<sup>5</sup> The new facility is designed to house biocontainment laboratories suitable for pathogens (disease-causing organisms) currently under investigation at Plum Island that cause foreign animal diseases, as well as for other exotic, high-

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<sup>3</sup>GAO, *Foot-and-Mouth Disease: USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened*, [GAO-19-103](#) (Washington, D.C.: Mar. 12, 2019).

<sup>4</sup>The White House, Homeland Security Presidential Directive-9, *Defense of United States Agriculture and Food* (Washington, D.C.: Jan. 30, 2004).

<sup>5</sup>For years, USDA owned and operated Plum Island, located in the Long Island Sound off the coast of New York. Scientists at Plum Island, often with the assistance of scientists from other countries, have diagnosed the pathogens that cause foreign animal diseases and then conducted research to, among other things, develop vaccines to protect against them. In 2003, DHS assumed ownership of the island and all its facilities.

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consequence pathogens that cause zoonotic foreign animal diseases.<sup>6</sup> NBAF is also designed to be the first such facility in the United States capable of housing cattle and other large livestock for the highest level of biocontainment. In addition, it is designed to house the Biologics Development Module, a laboratory intended to enhance and expedite the transition of vaccines and other countermeasures from research to commercial viability.<sup>7</sup>

In 2009, DHS, which is responsible for the construction of the new facility, selected Manhattan, Kansas, as the site, and in May 2015, DHS awarded the primary construction contract. In March 2017, DHS estimated that NBAF would cost about \$1.25 billion.

DHS originally assumed responsibility for operating NBAF. However, USDA will now carry out this responsibility. This change follows the President issuing an executive order from March 2017. The order directed the Office of Management and Budget to propose a plan to eliminate unnecessary federal agencies, components of agencies, and agency programs and to merge functions for greater efficiency.<sup>8</sup> In response, DHS evaluated its programs to determine what changes the department could make and, in coordination with the Office of Management and Budget, proposed transferring operational responsibility for NBAF from DHS to USDA.<sup>9</sup> Through the President's budget request for fiscal year 2019, the administration proposed transferring operational responsibility for NBAF from DHS to USDA, stating that because USDA is already responsible for the research programs that will be conducted at the facility, it makes sense for USDA to manage the facility. In March 2018, Congress provided the initial appropriations to USDA to support NBAF human capital development. In February 2019, Congress provided appropriations to USDA to support operations and carry out the science program. Congress also provided authority to the Administrators of the

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<sup>6</sup>Biocontainment is the containment of pathogenic organisms, such as viruses, usually by isolation in secure facilities to prevent their accidental release.

<sup>7</sup>The Biologics Development Module will be the first of its type for a U.S. government biocontainment facility. Commercially viable countermeasures include vaccines and diagnostics that are used to prevent, treat, or diagnose animal diseases.

<sup>8</sup>Executive Order No. 13781, Comprehensive Plan for Reorganizing the Executive Branch, 82 Fed. Reg. 13959 (Mar. 13, 2017).

<sup>9</sup>Office of Management and Budget, *Delivering Government Solutions in the 21st Century, Reform Plan and Reorganization Recommendations* (Washington, D.C. 2018).

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Agricultural Research Service (ARS) and the Animal and Plant Health Inspection Service (APHIS) to appoint up to 50 employees at NBAF for fiscal years 2019 through 2025.<sup>10</sup>

After DHS completes construction of NBAF and verifies that the facility's systems and components are fully operable and the facility functions as designed, DHS is to transfer ownership of NBAF to USDA, which will operate the facility. We reported in December 2019 that DHS NBAF officials said the transition introduces cost and schedule risks to the program because highly integrated activities, such as efforts to achieve operational capability, are now being managed by two different departments—DHS and USDA.<sup>11</sup> Questions have been raised by Members of Congress, however, about the change in plans for the facility, including potential effects on the future operation of NBAF, staffing, and collaboration with experts outside USDA.

You asked us to review issues related to the development of the facility and USDA's plans for operating it. This report examines (1) efforts to implement the transfer of ownership of NBAF from DHS to USDA and to prepare for the facility's operation and (2) USDA's efforts to collaborate with stakeholders.

To address both objectives, we interviewed key officials and reviewed relevant documents from DHS and USDA. We also reviewed documents from the animal health industry and public policy and scientific organizations, including the National Academy of Sciences.<sup>12</sup> In addition, we interviewed 15 stakeholders whom we judgmentally selected based on (1) their involvement with relevant reports from USDA and the National Academy of Sciences;<sup>13</sup> (2) their presence at the USDA conference of

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<sup>10</sup>Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, 133 Stat. 13, 36, 48, 51, 82.

<sup>11</sup>GAO, *Homeland Security Acquisitions: Outcomes Have Improved, but Actions Needed to Enhance Oversight of Schedule Goals*, [GAO-20-170SP](#) (Washington D.C.: Dec. 19, 2019).

<sup>12</sup>National Research Council, *Meeting Critical Laboratory Needs for Animal Agriculture: Examination of Three Options* (Washington D.C.: 2012) and *Evaluation of the Updated Site-Specific Risk Assessment for the National Bio- and Agro-Defense Facility in Manhattan, Kansas* (Washington D.C.: 2012).

<sup>13</sup>U.S. Department of Agriculture, Agricultural Research Service, *Henipavirus Gap Analysis Workshop Report* (Washington, D.C., Nov. 2018); National Research Council, *Meeting Critical Laboratory Needs for Animal Agriculture: Examination of Three Options*.

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NBAF stakeholders in Kansas City, Missouri, in May 2019;<sup>14</sup> or (3) the type of organization they represented, such as academic institutions and the animal health industry. Because this was a nongeneralizable sample of stakeholders, our results do not reflect the views of all nonfederal stakeholders who have studied issues related to NBAF's transfer, but they provide illustrative examples. We also attended the May 2019 conference to better understand USDA's efforts to operate the facility and coordinate with other federal and nonfederal stakeholders.

To examine efforts to implement the transfer of ownership of NBAF from DHS to USDA and to prepare for the facility's operation, we identified key practices for government reforms, including reorganizations, from our prior work and selected those most relevant to this transfer, including practices for implementing those efforts and strategically managing the federal workforce.<sup>15</sup> We reviewed documents about DHS's plans for the facility, including the construction schedule and cost estimates. We also reviewed documents from USDA related to the transfer of ownership of NBAF from DHS to USDA, and we interviewed officials from both departments about these efforts to transfer this facility. Further, we compared these efforts with the selected practices. We did not examine the basis for the decision to transfer the facility from DHS to USDA.

To examine USDA's efforts to collaborate with stakeholders, we identified key practices for collaboration from our prior work, and we selected those key practices that were most relevant to USDA's efforts.<sup>16</sup> We reviewed relevant documents—such as USDA policies, plans, and guidance—related to proposed plans to operate NBAF. We also reviewed the memorandums between USDA and DHS describing the two departments' roles and responsibilities before this transfer and after this transfer is complete. We interviewed officials from both departments about their

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<sup>14</sup>The USDA NBAF Stakeholders and Partnerships Conference was held from May 22 to 23, 2019, in Kansas City, Missouri.

<sup>15</sup>GAO, *Government Reorganization: Key Questions to Assess Agency Reform Efforts*, [GAO-18-427](#) (Washington, D.C.: June 13, 2018). In this report, we organized our prior work and key practices into four broad categories that can help assess agency reform efforts: goals and outcomes of reforms, process for developing reforms, implementing the reforms, and strategically managing the federal workforce. Reforming and reorganizing the federal government can include refocusing, realigning, or enhancing agency missions, as well as taking steps to improve services by identifying and eliminating inefficiencies. For the purpose of this report, we selected key practices related to implementing the reforms and strategically managing the federal workforce.

<sup>16</sup>GAO, *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, [GAO-12-1022](#) (Washington, D.C.: Sept. 27, 2012).

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efforts related to these key practices and then compared these efforts with the selected key practices.

We conducted this performance audit from July 2018 to July 2020 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

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## Background

USDA's strategic vision for NBAF describes NBAF's mission as providing an enduring capability to enable the United States to conduct comprehensive research, develop vaccines, and provide enhanced diagnostic and training capabilities to protect against transboundary, emerging, and zoonotic animal diseases that could threaten our nation's food supply, agricultural economy, and public health.<sup>17</sup> This mission is consistent with many of the directives of HSPD-9, which specifically references zoonotic and foreign animal diseases. The mission also relates to the execution of the National Biodefense Strategy, whose purpose is to develop a coordinated effort to protect the American people from biological threats.<sup>18</sup> For example, USDA's strategic vision describes the mission of the Biologics Development Module as to support and accelerate technology transfer (e.g., technology for vaccines, diagnostics, and veterinary medical countermeasures) to commercial veterinary biologics manufacturers.

Within USDA and DHS, three primary agencies have been responsible for developing NBAF:

- **DHS's Science and Technology Directorate** is the research and development arm of DHS. It focuses on providing tools and technologies to address homeland security needs. It has operated

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<sup>17</sup>U.S. Department of Agriculture, *NBAF: Creating a National Asset for America's Biosecurity Infrastructure* (Washington, D.C).

<sup>18</sup>Goals in the strategic vision related to the National Biodefense Strategy include Goal 2.1.5 to strengthen animal disease detection and prevention capacity, Goal 3.5.1 to improve diagnostic capabilities, and Goal 3.5.5 to enhance medical countermeasure development, sustainment, and availability. For information about GAO's efforts to assess the implementation of the National Biodefense Strategy, see [GAO-20-273](#) (Washington, D.C.; Feb. 19, 2020).

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Plum Island since 2003, when the Homeland Security Act of 2002 transferred ownership of Plum Island from USDA to DHS.<sup>19</sup> The directorate has been responsible for managing planning, design, and construction activities for NBAF; the directorate will remain responsible for these activities until construction is complete and DHS has verified that the facility's systems and components are fully operable and the facility functions as designed.<sup>20</sup> Before the more recent proposed transfer of NBAF to USDA, the directorate's intended role at NBAF was to operate the facility and help transition products, such as vaccines, developed through NBAF to the animal health industry for regulatory licensure and manufacturing.

- **USDA's Agricultural Research Service (ARS)** is USDA's chief scientific in-house research agency, and its mission is to deliver scientific solutions to national and global agricultural challenges. At Plum Island, ARS has performed basic and applied research for foreign animal diseases. At NBAF, ARS intends to perform research on foreign animal diseases and develop medical countermeasures, such as vaccines.
- **USDA's Animal and Plant Health Inspection Service (APHIS)** has the mission to safeguard the health and welfare of American agriculture and natural resources. APHIS does so in part by conducting diagnostic laboratory activities to support veterinary disease prevention, detection, control, and eradication programs. APHIS's role at Plum Island has been to conduct diagnostics and training for detection of foreign animal diseases. This role is intended to continue at NBAF.

All of the diseases intended for study at NBAF are foreign animal diseases, according to USDA documents. With NBAF, USDA seeks to expand the type and number of such diseases it will investigate. Specifically, NBAF is designed to allow USDA to expand its research of foreign animal diseases to include zoonotic diseases, increasing the number of foreign animal diseases under investigation from the three at

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<sup>19</sup>Pub. L. No. 107-296, § 310, 116 Stat. 2135, 2174 (2002) (codified at 6 U.S.C. § 190).

<sup>20</sup>Verification that the facility's systems and components are fully operable and the facility functions as designed is known as completion of commissioning. DHS retained a third-party commissioning agent, and a commissioning plan has been in place since 2012.

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Plum Island to seven at NBAF, as shown in table 1.<sup>21</sup> (For more detailed information about each of these diseases, see app. I.) All except one of the pathogens causing these diseases—the pathogen for Japanese encephalitis—are designated as “select agents” per federal regulation because they have the potential to pose a severe threat to human and animal health and safety, or to animal and plant products.<sup>22</sup>

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<sup>21</sup>This list of diseases differs from the list included in USDA’s strategic vision for NBAF. Specifically, it includes Crimean-Congo Hemorrhagic fever and excludes the Ebola virus. In December 2019, USDA officials told us they have continued evaluating the diseases they should focus on and have added Crimean-Congo Hemorrhagic fever to the list. USDA officials told us that they may still use NBAF to study the Ebola virus, which is considered an emerging zoonotic disease, but it does not pose an imminent threat to livestock, and livestock have not been implicated in outbreaks. Symptoms of Ebola virus in humans include fever, headache, muscle pain, weakness, diarrhea, vomiting, and unexplained bleeding or bruising. It is often fatal.

<sup>22</sup>7 C.F.R. pt. 331; 9 C.F.R. pt. 121; 42 C.F.R. pt. 73. Also, for the purposes of this report, we use the term “select agents” to encompass both designated agents and toxins. As of May 2020, 67 agents and toxins had been designated as “select agents and toxins”—that is, needing specific types of safeguards and oversight.

**Table 1: Foreign Animal Diseases Planned for Study at the National Bio and Agro-Defense Facility (NBAF)**

Disease	Description
<b>Currently studied at Plum Island Animal Disease Center</b>	
<b>African swine fever</b>	A highly contagious and deadly virus affecting both domestic and wild pigs. Symptoms in pigs include high fever, red, blotchy skin or skin lesions, diarrhea, and vomiting.
<b>Classical swine fever</b>	A highly contagious virus of pigs; the severity varies with the strain of the virus, age of the pig, and immune status of the herd. Symptoms in pigs include high fever, reddened eyes, and hemorrhages with discoloration of the ears, abdomen, or inner thighs.
<b>Foot-and-mouth disease</b>	A virus of cows, pigs, sheep, goats, deer, and other animals with cloven hooves. Symptoms in these animals include fever, lameness, and blisters on the feet and mouth. There are seven known types and more than 60 subtypes, and immunity to one type does not protect against others. Considered one of the most contagious, infectious diseases.
<b>Zoonotic diseases planned for study at NBAF<sup>a</sup></b>	
<b>Crimean-Congo Hemorrhagic fever</b>	A virus transmitted by ticks. Although humans are the main host affected by this virus, cattle, goats, sheep, and hares are also hosts of the virus. Symptoms in humans include headache, high fever, back pain, joint pain, stomach pain, and vomiting. Symptoms may also include jaundice, and in severe cases, changes in mood and sensory perception.
<b>Japanese encephalitis</b>	A virus that can affect pigs, horses, birds, cattle, sheep, dogs, cats, reptiles, amphibians, and humans. Most common symptoms in pigs are stillborn or mummified fetuses. Pigs not pregnant do not typically show signs of infection or experience only mild transient fever. Symptoms in horses, though, include fever, anorexia, lethargy, blindness, coma, and death. Horses that recover may continue to have neurological problems. Most infected people do not have symptoms or have only mild symptoms, but a small percentage of infected people develop inflammation of the brain (encephalitis), with symptoms including sudden onset of headache, high fever, disorientation, coma, tremors, and convulsions. About 20 percent to 30 percent of infected people who develop encephalitis die. Some people who survive continue to have neurologic, cognitive, or psychiatric symptoms.
<b>Nipah virus</b>	A virus that causes disease primarily in swine and humans. In a 1999 outbreak in Malaysia and Singapore, the virus caused a relatively mild disease in pigs, but nearly 300 human cases with over 100 deaths were reported. There have been no additional outbreaks in Malaysia or Singapore. However, in 2001, outbreaks occurred in Bangladesh and India, and several outbreaks have occurred since in Bangladesh and India. Symptoms in humans include respiratory illness, fever, headache, encephalitis, neurological damage, coma, and death.
<b>Rift Valley fever</b>	An acute, fever-causing virus most commonly observed in domesticated animals (such as cattle, buffalo, sheep, goats, and camels), but which can also infect and kill humans. In cattle, symptoms include weakness, depression, diarrhea, low milk yield, and high abortion rates in pregnant cows. In sheep and goats, symptoms include weakness, depression, vomiting, diarrhea, and abortion rates approaching 100 percent. In humans, symptoms include headache, weakness, light sensitivity, blindness, and death. Less than 1 percent of cases in humans are fatal.

Sources: U.S. Department of Agriculture (USDA) and Centers for Disease Control and Prevention. | GAO-20-331

Note: All diseases to be studied at the National Bio and Agro-Defense Facility are foreign animal diseases—diseases not known to be present in the United States—and some of these diseases are zoonotic (i.e., they can be transmitted between animals and humans).

<sup>a</sup>According to USDA officials in March 2020, USDA has identified research it could conduct on COVID-19, and this research can be conducted in its existing facilities, such as the Southeast Poultry Research Laboratory in Georgia and the National Animal Disease Center in Iowa.

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The main laboratory building at NBAF is designed to provide 574,000 square feet of space for research and diagnostic laboratories, training facilities, and animal and support spaces. According to USDA officials, the annual cost for operations and maintenance of the facility and the science program there is estimated to be about \$200 million once the facility is operational.<sup>23</sup> Figure 1 shows the construction site of NBAF and what the completed facility is to look like.

**Figure 1: Construction Site of the National Bio and Agro-Defense Facility (NBAF) as of November 2019 and an Artist's Rendering of NBAF When Complete**



Source: Department of Homeland Security and NBAF Design Partnership. | GAO-20-331

NBAF is to consist of multiple biocontainment laboratories and related spaces classified into three biological safety levels (BSL) to serve different purposes, according to USDA documentation.<sup>24</sup>

- The BSL-2 laboratories (6 percent of available space) are intended to maintain and provide cell lines for use in the diagnostic and research laboratories.<sup>25</sup> These cell lines are intended to provide the necessary base for growth of viruses to develop methods to quickly diagnose and control the spread of animal diseases. Scientists work in carefully

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<sup>23</sup>The estimated annual cost for operations and maintenance of NBAF and the science program includes utilities, salaries of staff, training, supplies and equipment, site security, and anticipated capital improvements, according to USDA officials.

<sup>24</sup>Biological safety—or biosafety—is the application of safety precautions that reduce a laboratory worker's risk of exposure to a potentially infectious microbe and limit contamination of the work environment and, ultimately, the community.

<sup>25</sup>A cell line is a cell culture selected for uniformity from a cell population derived from a usually homogeneous tissue source, such as an organ.

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controlled areas to ensure cell lines are maintained clean and pathogen-free.

- The BSL-3E (Enhanced) laboratories (23 percent of available space) are intended for conducting and developing analyses for disease detection and for basic and applied research leading to development of countermeasures.
- The BSL-3Ag (Agriculture) spaces (23 percent of available space) are intended to house the animals where veterinarians and animal care staff attend to the animals' needs. These spaces are also intended for understanding how animal diseases spread among large livestock populations to learn how to prevent, diagnose, and control diseases within the animals themselves.
- The BSL-4 laboratory (8 percent of available space) is intended to allow work to be done with pathogens that could cause severe to fatal disease in humans, including zoonotic animal diseases. Special procedures and equipment, such as fully contained suits with dedicated air supply, are necessary to work within this space.

One of NBAF's laboratories is to be the Biologics Development Module (5 percent of available space). This module is intended to mitigate risks to U.S. agriculture by enhancing and expediting the transition of vaccines and other countermeasures from research to commercial viability. According to a USDA briefing document, this transition can currently take multiple years. For example, finalizing a cooperative research and development agreement with industry and issuing a license to develop technology can take over 2 years, and obtaining permission to conduct research on a lower-risk form of a select agent to develop a vaccine in an industry facility can take over 4 years.<sup>26</sup>

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<sup>26</sup>Select agent regulations (7 C.F.R. pt. 331, 9 C.F.R. pt. 121, and 42 C.F.R. pt. 73) include a procedure by which an attenuated strain of a select biological agent or toxin that does not pose a severe threat to plant health or plant products, animal health or animal products, or public health and safety may be excluded from the requirements of the select agent regulations.

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## DHS and USDA Have Taken Steps to Transfer Ownership of NBAF to USDA and Prepare for the Facility's Operation, but Critical Steps Remain

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### DHS and USDA Have Taken Steps to Plan for and Implement the Successful Transfer of Ownership of NBAF and Strategically Prepare for Its Operation

DHS and USDA have taken steps to plan for and implement the successful transfer of ownership of NBAF and to prepare for its operation, such as by developing a dedicated implementation team and an implementation plan. Our prior work has shown that incorporating such key practices improves the likelihood of success for government reforms—in this case, the transfer of NBAF to USDA.<sup>27</sup> The departments' steps are consistent with selected key practices we examined for implementation of government reforms. In addition, USDA has taken steps to identify and fill staffing needs for the facility; these efforts are consistent with other selected key practices we examined for strategically managing the federal workforce during a government reorganization.

Table 2 below summarizes selected key practices we examined for successful implementation of government reforms, and provides examples of relevant steps by DHS or USDA:

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<sup>27</sup>GAO, *Results-Oriented Cultures: Implementation Steps to Assist Mergers and Organizational Transformations*, [GAO-03-669](#) (Washington, D.C.: July 2, 2003).

**Table 2: Selected Key Practices for Implementing Government Reforms and Examples of Relevant Department Efforts to Transfer Ownership of the National Bio and Agro-Defense Facility (NBAF) and Prepare for the Facility’s Operation, as of April 2020**

Key practice	DHS and USDA efforts
Developing a dedicated implementation team and designating leaders responsible for the reform	<p>The Department of Homeland Security (DHS) and USDA have given Plum Island’s board of directors and Executive Steering Committee responsibility for leading the transfer of operations to NBAF. The board of directors and this committee provide interagency forums for operational planning, partnerships, and transitioning programs and activities from Plum Island to NBAF.</p> <p>USDA established the NBAF Executive Council to ensure effective operations and management of NBAF, and that appropriate resources and personnel are in place to meet current and upcoming needs.</p> <p>USDA established a transition leadership team within USDA comprised of top leaders in both its Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS); these leaders can make key decisions and provide guidance needed to proceed with USDA’s efforts to achieve full operational capability for NBAF.</p> <p>To help identify and implement the activities needed to obtain full operational capability, USDA and DHS have formed working groups that include USDA and DHS officials and also contractor support personnel. They also established a coordinating body for these groups, which include DHS, APHIS, and ARS leadership in Manhattan, Kansas, according to USDA officials. Each of these working groups represents major functional, technical, or support areas needed to obtain full operational capability. The areas covered by these working groups include biorisk management, budget, communications, facilities, human resources and personnel security, information technology, and physical security.</p>
Developing an implementation plan with key milestones and deliverables to track implementation progress	<p>In August 2018, USDA started developing an implementation plan in the form of an integrated master schedule. This schedule connects all the scheduled work in a collection of logically linked sequence of activities to monitor progress on all the activities for NBAF.<sup>a</sup> This schedule spans 15 technical domains, such as physical plant services, NBAF security, information technology management, and standard operating procedures. Department officials stated that this schedule has continued to be refined through meetings with technical working group members, scheduling experts, and the DHS construction team. Officials from DHS and USDA stated that the departments are assessing the effects of the COVID-19 pandemic on the schedule.</p>

Sources: [GAO-18-427](#), as well as GAO analysis of Department of Homeland Security and U.S. Department of Agriculture (USDA) information. | GAO-20-331

<sup>a</sup>For more information about integrated master schedules, see GAO, *Schedule Assessment Guide: Best Practices for Project Schedules*, [GAO-16-89G](#) (Washington, D.C.: December 2015).

To identify and fill staffing needs for the facility, USDA has taken steps to determine if the department will have the needed skills and competencies in place, and to develop strategies to recruit and hire highly specialized and hard-to-fill positions. These efforts address selected key practices that we examined for strategically managing the federal workforce during a government reorganization. The key practices we examined and examples of relevant USDA efforts are summarized in table 3 below.

**Table 3: Selected Key Practices for Government Reforms and Examples of Relevant USDA Efforts to Strategically Manage the Federal Workforce for the National Bio and Agro-Defense Facility (NBAF), as of April 2020**

Key practice	USDA efforts
Determining whether it will have the needed resources and capacity, including the skills and competencies, in place for the proposed reforms or reorganization	USDA used various working groups, such as working groups for budget, communications, facilities, information technology, and physical security, as well as subject matter experts to determine necessary critical skills and competencies. Using input from these working groups, USDA developed its operational model for the facility. USDA is monitoring its progress toward its hiring goals. Officials from the Agricultural Research Service and Animal and Plant Health Inspection Service stated that they met their hiring goals for fiscal year 2019.
Developing strategies to recruit and hire highly specialized and hard-to-fill positions	To help recruit and hire highly specialized and hard-to-fill positions, USDA has taken various approaches, such as using direct-hire authority to hire facilities staff and engineering staff, recruiting existing contractor staff performing facilities-type work to retain specialized skill sets for maintaining and operating NBAF, and developing training programs for new scientists.
Including accountability for proposed change implementation in performance expectations and assessments of leadership and staff	USDA has included the successful transfer and stand-up of NBAF in performance standards for its leaders and other staff involved with the effort, according to USDA officials.

Sources: GAO-18-427 and GAO analysis of U.S. Department of Agriculture (USDA) information. | GAO-20-331

As shown in table 3, USDA has relied on various working groups—such as working groups for budget, communications, facilities, information technology, and physical security—and subject matter experts to help determine if the department will have the needed resources and capacity to staff the facility.<sup>28</sup> The working groups provided advice and guidance regarding skill sets needed, position descriptions, and overall full-time equivalent positions for the final, approved staffing plans, according to USDA officials.<sup>29</sup>

USDA plans to use a predominantly federal workforce—mainly USDA staff<sup>30</sup>—for NBAF. This approach contrasts with DHS’s original plans,

<sup>28</sup>Officials stated in December 2019 that they were uncertain how many staff would relocate. However, officials also stated that USDA and DHS held a joint meeting in March 2020 in which agency leadership and human resource staff were available to discuss opportunities with staff about NBAF.

<sup>29</sup>A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees, divided by the number of compensable hours applicable to each fiscal year.

<sup>30</sup>USDA officials told us they plan to coordinate with other federal scientists to support collaborative research.

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which would have relied largely on contractors. (See app. II for a comparison of DHS's and USDA's plans for NBAF.) DHS had planned to undertake certain roles at NBAF itself, and APHIS and ARS now plan to undertake those roles. For example, APHIS plans to establish a new functional science section that is to coordinate diagnostic development, while ARS intends to conduct late-stage research and development, testing, and evaluation.<sup>31</sup> USDA plans to supplement federal staff with science fellows, graduate students, visiting scientists, and other experts. In contrast to NBAF's overall operations, USDA intends to operate the Biologics Development Module with USDA contractors. Doing so will enable flexibility in meeting specialized workforce needs, according to USDA documentation.

In keeping with its staffing plans, USDA has hired several key leadership officials for NBAF, including the NBAF Director; Biorisk Manager; NBAF Coordinator; and Safety, Health, and Environmental Manager. In addition, some DHS officials onsite at NBAF became USDA employees in September 2019, including the Security Director and Information Technology Director.

To help achieve USDA's hiring goals for NBAF, USDA officials stated they have taken various approaches, such as using direct-hire authority, recruiting existing contractor staff, and establishing a science-training program. (For more information about these approaches, see app. III.) USDA officials stated that they achieved their hiring goals for fiscal year 2019, including filling 66 positions in ARS and 43 positions in APHIS. The ARS positions included the NBAF Director and positions in other areas, such as facilities, biorisk, administration, and animal resources.<sup>32</sup> The APHIS positions were in areas such as information technology, training and standard operating procedures management, administration, and laboratory support services.

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<sup>31</sup>DHS's previous plans included using a mixture of federal contract positions, research fellows, trainees, visiting scientists, and collaborators from industry and academia. DHS scientific and support staffing would have included a small cadre of federal supervisory staff, with oversight of contract personnel. According to a DHS NBAF official, DHS intended to hire a contractor to perform a staffing analysis to determine the necessary critical skills and competencies for NBAF.

<sup>32</sup>Biorisk is the combination of the probability of occurrence of harm and the severity of harm where the source of harm is a biological agent.

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**Critical Steps Remain to Implement the Transfer of Ownership and Prepare for the Facility's Operation, and Some Efforts Have Been Delayed**

Critical steps remain to implement the transfer of ownership of NBAF to USDA and prepare for the facility's operation, and some efforts have been delayed. As noted previously, before the transfer can be achieved, DHS must complete construction of NBAF and verify that the facility's systems and components are fully operable and the facility functions as designed. In April 2020, the DHS NBAF Program Manager stated that construction of NBAF has been delayed by at least 2.5 months because of the effects of the COVID-19 pandemic on availability of labor and materials, but also stated that the forecasted delay is based on changing circumstances and may likely increase. Before this delay, the milestones for constructing the facility and preparing for operations were as follows, according to USDA documents:

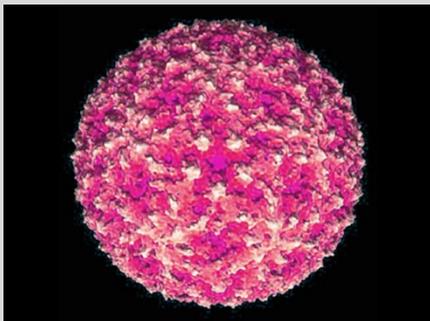
### Federal Select Agent Program

Under the Select Agent Program, agencies regulate the possession, use, and transfer of select agents. Currently, 67 pathogens and toxins are regulated as “select agents” under this program because they have the potential to pose a severe threat to human and animal health and safety, or to animal and plant products. The program is jointly managed by the Division of Select Agents and Toxins within the Department of Health and Human Services’ Centers for Disease Control and Prevention (CDC) and the Agriculture Select Agent Services within the U.S. Department of Agriculture’s Animal and Plant Health Inspection Service (APHIS). Together, these components within CDC and APHIS regulate and oversee all laboratories in the United States that register to work with select agents.

Generally, laboratories (including those at federal agencies and private institutions) and individuals who possess, use, or transfer these select agents must register with CDC or APHIS and renew their registration every 3 years.

To apply for a certificate of registration, the laboratory must submit an application package to either CDC or APHIS, and laboratory personnel must submit to a security risk assessment conducted by the Federal Bureau of Investigation. The Select Agent Program conducts an on-site inspection before issuing a new certificate of registration.

### Foot-and-mouth disease virus



Sources: GAO-18-145, Federal Select Agent Program and U.S. Department of Agriculture. | GAO-20-331

- **December 2020: DHS to complete construction.**
- **May 2021: DHS to achieve the initial operational capability.** This milestone entails verification that NBAF systems and components are fully operable and that the facility functions as designed. This milestone is also known as completion of “commissioning.”
- **December 2022: USDA to have all certifications in place for NBAF to work with high-consequence pathogens.** These certifications include a certificate of registration for the NBAF laboratory spaces through the Federal Select Agent Program (Select Agent Program) to work with biological agents that have the potential to pose a severe threat to public health and safety—known as select agents—such as the viruses that cause African swine fever and foot-and-mouth disease (see sidebar). USDA must also have a permit from the Secretary of Agriculture to transfer live foot-and-mouth disease virus from Plum Island to NBAF.<sup>33</sup> With these certifications, USDA will consider the facility to have achieved full operational capability. This milestone is not dependent on completion of all preparations for the Biologics Development Module, according to USDA officials.
- **August 2023: Full transition of operations from Plum Island to NBAF.** According to the DHS NBAF official who notified us of the delay, work at the site continues, but the forecast delay may increase, depending on changing circumstances. The official stated that current uncertainties limit the ability to provide reliable forecasts for revised milestone dates; thus revised dates will not be established before some degree of stabilization of the issues leading to the delay.

USDA officials stated that, until the full effects of the delays to the construction and commissioning of NBAF are known, USDA cannot fully assess the effects on its efforts to prepare for the facility’s operation, including achieving full operational capability for the facility in December 2022. USDA has ongoing efforts to complete several steps that it considers to be on the “critical path” for facility preparations—the longest series of interconnected activities that will ultimately affect and determine the final project completion date. The status of these steps is described below:

<sup>33</sup>Possession of live foot-and-mouth disease virus has been restricted to Plum Island by law, 21 U.S.C. 113a, but the 2008 Farm Bill (Pub. L. No. 110-246 § 7524(a)), directed the Secretary of Agriculture to issue a permit to transfer the virus from Plum Island to NBAF.

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- **Implementing the information technology (IT) systems.** According to USDA officials and documents, USDA identified the IT requirements for NBAF by early 2019 and, in September 2019, purchased a system to manage biological inventory to help transfer the biorepository from Plum Island to NBAF. As of April 2020, this system had been installed, according to USDA officials, and the department was in the process of securing and evaluating other software systems to meet NBAF needs. In May 2020, USDA officials stated that the COVID-19 pandemic has not affected the time frame or plans for implementing the IT systems.
  - **Obtaining approvals to work with high-consequence pathogens.** USDA officials stated that USDA has planned its approach to obtain the necessary approvals to work with high-consequence pathogens, including obtaining the certificate of registration through the Select Agent Program and a permit from the Secretary of Agriculture to transfer live foot-and-mouth disease from Plum Island to NBAF. We have previously reported significant delays with other facilities in steps necessary to obtain certificates of registration, such as delays of a year or more to obtain approval for major changes to facilities, including addition of new laboratory space.<sup>34</sup> However, USDA officials told us that they have been frequently collaborating with officials from the Select Agent Program, such as through bi-weekly meetings. They stated that these efforts have been helpful in allowing USDA to plan for and address various areas of registration to ensure that USDA will be able to provide related timely documents. The officials also said that these efforts are enabling USDA to establish the process for facility inspections, review of commissioning documents, and laboratory inspections, among other things. In May 2020, USDA officials stated they cannot fully assess the effect of the COVID-19 pandemic on this effort.
  - **Transferring the pathogens from Plum Island to NBAF.** Scientists at Plum Island and subject matter experts from the USDA contractor team and others developed a draft plan to transfer the pathogens and associated data from Plum Island to NBAF. The draft plan, dated December 2019, includes proposed procedures for preparing pathogens at Plum Island for transport; for transporting those pathogens to NBAF; and for accepting them at NBAF. The plan states that next steps include collecting substantial information from and collaborating with USDA leadership and staff, and also coordinating

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<sup>34</sup>GAO, *High-Containment Laboratories: Coordinated Actions Needed to Enhance the Select Agent Program's Oversight of Hazardous Pathogens*, [GAO-18-145](#) (Washington, D.C.: Oct. 19, 2017).

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with other relevant entities on activities to physically transport the pathogens. Also, the DHS NBAF Program Manager stated that the planning to transfer the pathogens has been coordinated with DHS, which will retain the regulatory responsibility for the pathogens until they are removed from Plum Island. USDA officials told us that they intend to update the plan as they move forward with this effort, but they cannot fully assess the effect of the COVID-19 pandemic on this plan.

According to USDA officials, the steps on the critical path were on schedule before the onset of the COVID-19 pandemic. However, planning for the Biologics Development Module, which USDA does not consider to be on the critical path, was delayed before the pandemic. The integrated master schedule from November 2018 called for USDA to develop the business model and operating plan for the Biologics Development Module by the end of calendar year 2019. USDA missed this deadline, and the updated schedule from March 2020—prepared before USDA told us about the potential delays because of the COVID-19 pandemic—did not provide a time frame for when the business model and operating plan would be finalized or when USDA would begin operating the module. Officials stated in May 2020 that USDA intends to develop the business model and operating plan for the module, and seek feedback on them, by the end of fiscal year 2020. However, officials also stated that they cannot fully assess the effects of the COVID-19 pandemic on USDA's ability to begin operating the module.

Concerning staffing, USDA expects to have 421 full-time equivalent positions for NBAF once the facility is fully staffed, according to USDA documentation. (For more information about USDA's staffing projections, see app. IV.) USDA officials told us they were on track with the department's hiring goals for fiscal year 2020, as of May 2020. However, they also said they are reassessing quarterly targets for fiscal years 2020 and 2021 given the effects of the COVID-19 pandemic on NBAF construction and potential effects on other milestones.

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## USDA Has Taken Steps to Collaborate with Key Federal and Industry Stakeholders, including DHS, on an Ongoing Basis

### International Research Groups That Work on Topics Relevant to the National Bio and Agro-Defense Facility

USDA participates in international global research groups, including the following:

- Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses is a global network of animal disease research funders and researchers established to improve coordination of research activities on major infectious diseases of livestock and zoonoses to reduce duplication of global research efforts.
- The Global Foot-and-Mouth Disease Research Alliance was established in 2003 and is a worldwide association of animal research organizations involved in combating foot-and-mouth disease. The intent is to build a global alliance of partners to generate and share knowledge to develop tools that can better combat the threat of the disease.
- The mission of the Global African Swine Fever Research Alliance is to establish and sustain global research partnerships that will generate scientific knowledge and tools to contribute to the successful prevention, control and, where feasible, eradication of the disease.

Source: U.S. Department of Agriculture (USDA). | GAO-20-331

USDA's efforts to collaborate with stakeholders—such as DHS, other federal agencies, and the animal health industry—for NBAF include

- meeting regularly with DHS officials to define and articulate mission and research priorities,
- developing written agreements with DHS about DHS's roles and responsibilities before and after the transfer, and
- collaborating with the intelligence community, as well as international research groups and global alliances, on an ongoing basis.

For example, USDA participates in networks of laboratories internationally, and with global research groups such as the Global Strategic Alliances for the Coordination of Research on the Major Infectious Diseases of Animals and Zoonoses;<sup>35</sup> the Global Foot-and-Mouth Disease Research Alliance; and the Global African Swine Fever Research Alliance (see sidebar).

These efforts to date are consistent with selected key practices we examined for interagency collaboration.<sup>36</sup> Table 4 below summarizes the selected key practices and provides examples of USDA efforts that are consistent with these practices.

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<sup>35</sup>Zoonoses are also known as zoonotic diseases, which are infectious diseases that can be transmitted between animals and humans.

<sup>36</sup>See [GAO-12-1022](#) for further information on such key practices.

**Table 4: Selected Key Practices for Interagency Collaboration and Examples of Relevant USDA Efforts to Collaborate with Stakeholders for the National Bio and Agro-Defense Facility (NBAF), as of April 2020**

Selected key practice	USDA efforts
Outcomes and Accountability: Clearly defining short-term and long-term outcomes, and monitoring progress	<p>USDA and the Department of Homeland Security (DHS) are developing a process to define and articulate the priorities for the homeland security mission and for research to advance bio- and agro-security. Elements of the process include:</p> <ul style="list-style-type: none"> <li>USDA and DHS plan to hold annual joint “homeland security” meetings that include DHS’s National Biodefense Analysis and Countermeasures Center and representatives from other federal partners in the bio- and agro-defense domain.<sup>a</sup></li> <li>DHS plans to participate in annual NBAF stakeholder meetings to gather comments and provide guidance regarding NBAF research priorities.</li> </ul>
Clarity of roles and responsibilities: Participating departments clarifying roles and responsibilities	<p>USDA has taken steps to determine and document its roles and responsibilities for NBAF alongside other departments. For example:</p> <ul style="list-style-type: none"> <li>USDA and DHS developed a memorandum of agreement in June 2019 detailing departments’ responsibilities for standing up NBAF.</li> <li>USDA and DHS developed a memorandum of understanding in January 2020 that describes DHS’s formal role and responsibilities at NBAF and specific areas of collaboration between the two departments.</li> </ul>
Participants: Including all relevant participants in the collaborative effort	<p>USDA has taken steps to include relevant participants. For example, USDA:</p> <ul style="list-style-type: none"> <li>developed the NBAF operational model by using contributions and recommendations from DHS, subject matter experts, leadership from similar institutions, and contractor support personnel;</li> <li>meets quarterly with agencies from the Foreign Animal Disease Threat Interagency Working Group to keep the transboundary and emerging animal disease community updated and informed;<sup>b</sup></li> <li>has engaged in regional partnerships, U.S. partnerships, and global alliances;</li> <li>regularly communicates with the Kansas Intelligence Fusion Center to receive classified briefings and share intelligence products;<sup>c</sup></li> <li>has leveraged a working group, called the Defense Against Agroterrorism Working Group, to improve coordination between the agricultural and intelligence communities including the Federal Bureau of Investigation, Central Intelligence Agency, and DHS;</li> <li>plans to collaborate with USDA’s National Institute of Food and Agriculture on complementary extramural research, extension, and education programs;<sup>d</sup></li> <li>plans to collaborate with other domestic and international biocontainment facilities, such as DHS’s National Biodefense Analysis and Countermeasures Center; other USDA facilities; Kansas State University’s Biosecurity Research Institute; and laboratories in Australia, Canada, Germany, Mexico, and the United Kingdom;</li> <li>has been collaborating with state and local partners, such as by participating in annual exercises with the Kansas Department of Agriculture regarding emergency response; and</li> <li>held a conference with federal and industry stakeholders in May 2019 to obtain feedback about its plans for NBAF.</li> </ul>
Written guidance and agreements: Participating departments documenting their agreement regarding how they will collaborate	<p>USDA has developed memorandums with DHS and the Department of Justice’s Federal Bureau of Investigation, as discussed above in “Clarity of roles and responsibilities.”</p>

Sources: [GAO-12-1022](#) and GAO analysis of U.S. Department of Agriculture (USDA) information. | GAO-20-331

<sup>a</sup>The National Biodefense Analysis and Countermeasures Center is intended to help defend the country against biological threats by supporting intelligence assessments, preparedness planning, response, emerging threat characterization, and bioforensic analyses.

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<sup>b</sup>USDA officials stated that the working group has continued to meet even though it was not re-chartered after 2018. The group is co-chaired by APHIS and ARS, and attendees include the Centers for Disease Control and Prevention, Department of Defense, Defense Threat Reduction Agency, Department of Homeland Security, Department of the Interior, Department of State, Environmental Protection Agency, and National Institutes of Health.

<sup>c</sup>The Kansas Intelligence Fusion Center's mission is to generate intelligence analysis for homeland security policy and relevant threat warnings for Kansas and the surrounding region.

<sup>d</sup>The National Institute of Food and Agriculture is a federal agency within USDA and is part of USDA's Research, Education, and Economics mission area. The agency administers federal funding to address the agricultural issues.

As shown in table 4, DHS and USDA developed a memorandum of understanding in January 2020 describing DHS's formal roles and responsibilities at NBAF as well as specific areas of collaboration between the two departments. For example, the memorandum states that DHS's responsibilities will include conducting analyses to determine the scope and impact of potential biological events through modeling and simulation studies, participating as a member of the NBAF board of directors, and maintaining a strategic presence at NBAF to support national security priorities related to the NBAF mission. According to the memorandum, this presence may include

- a scientific program manager to (1) develop DHS agricultural defense strategic and tactical research and development plans, (2) manage the DHS agricultural defense countermeasure portfolio, and (3) serve as a liaison to the NBAF director, and
- a scientific advisor to (1) manage a DHS countermeasure-prototyping program, (2) manage transition of projects to industry partners, and (3) serve as a liaison with NBAF research leaders.

Areas of collaboration between USDA and DHS described in the memorandum include risk assessments, prioritization of research, characterization of threats, and development of countermeasures. (For more information about USDA's and DHS's responsibilities at NBAF, see app. V).

To include additional relevant participants—such as stakeholders at other federal agencies and in the animal health industry—in its collaborative efforts, USDA developed the NBAF operational model by using contributions and recommendations from DHS, subject matter experts, leadership from similar institutions, and contractor support personnel. These participants helped USDA incorporate practices found in private industry, academia, and similar institutions, according to a USDA

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document. In addition, USDA held a conference in May 2019 to share information about USDA's priorities and capabilities at NBAF and to obtain feedback on opportunities for collaboration. USDA officials told us in May 2020 that USDA plans to continue collaborating with stakeholders using virtual options where possible for the foreseeable future.

The animal health industry and other stakeholders are interested in working with USDA on NBAF and the Biologics Development Module, according to stakeholders we interviewed. For example, industry members expressed interest in working with USDA on early proof-of-concept work and safety studies for particular vaccines; production of antigen for a vaccine bank for foot-and-mouth disease or other pathogens; and testing disinfectants aimed at foreign animal diseases.

Regarding the Biologics Development Module, some industry representatives told us they have appreciated USDA's efforts so far in sharing information about it with stakeholders. However, some industry representatives told us they are uncertain about how the Biologics Development Module will operate. Stakeholders said that additional information on how the module is to operate would be beneficial, such as information on the number of projects to be undertaken concurrently in the module, on how USDA plans to prioritize prospective projects, and on how USDA intends to ensure that companies of all sizes are able to use the module. Stakeholders made similar comments at the USDA conference of NBAF stakeholders in May 2019, according to the conference report. According to that report and USDA officials we interviewed, USDA plans to continue working with stakeholders to clarify these uncertainties and to request feedback, such as through additional conferences with stakeholders.

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## Agency Comments

We provided a draft of this report to USDA and DHS for review and comment. In USDA's comments, reproduced in appendix VI, USDA agreed that critical steps remain to complete the transfer of NBAF to USDA and to prepare for the facility's operation. In addition, USDA and DHS provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretaries of Agriculture and Homeland Security, and other interested parties. In addition, the report will be available at no charge on the GAO website at <http://www.gao.gov>.

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If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or [morriss@gao.gov](mailto:morriss@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 VII.

A handwritten signature in black ink that reads "Steve D. Morris". The signature is written in a cursive, slightly slanted style.

Steve D. Morris  
Director, Natural Resources and Environment

# Appendix I: Diseases Planned for Study at the National Bio and Agro-Defense Facility

All diseases to be studied at the National Bio and Agro-Defense Facility are foreign animal diseases—diseases not known to be present in the United States—and some of these are zoonotic (i.e., they can be transmitted between animals and humans).

**Table 5: Foreign Animal Diseases Planned for Study at the National Bio and Agro-Defense Facility (NBAF)**

Disease	Description
<b>Currently studied at Plum Island Animal Disease Center</b>	
<b>African swine fever</b>	<p>A highly contagious and deadly virus affecting both domestic and wild pigs. Symptoms in pigs include high fever, red, blotchy skin or skin lesions, diarrhea, and vomiting.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> Cannot be transmitted from pigs to humans; is not a food safety issue.</li> <li>• <b>Location:</b> Found in sub-Saharan Africa, China, Mongolia, Vietnam, and parts of the European Union.</li> <li>• <b>Consequences:</b> An outbreak would have a significant effect on U.S. livestock producers, their communities, and the economy.</li> <li>• <b>Countermeasures:</b> Treatment or vaccine is not available. The only way to stop this disease is to depopulate all affected or exposed herds of swine.</li> </ul>
<b>Classical swine fever</b>	<p>A highly contagious virus of pigs; the severity varies with the strain of the virus, age of the pig, and immune status of the herd. Symptoms in pigs include high fever, reddened eyes, and hemorrhages with discoloration of the ears, abdomen, or inner thighs.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> Pigs are generally infected by the oral or nasal routes, but the virus can also enter via other mucus membranes or skin abrasions. It can be transmitted to healthy pigs through contact with contaminated vehicles, pens, feed, or clothing. It cannot be transmitted from pigs to humans.</li> <li>• <b>Location:</b> Previously widespread, but many countries have eradicated it from domesticated swine, including the United States in 1978.</li> <li>• <b>Consequences:</b> An outbreak would have serious consequences for domestic and international trade of swine and swine products.</li> <li>• <b>Countermeasures:</b> Vaccines are available, but there is no treatment other than supportive care. Pigs that recover may serve as infection risk to unaffected pigs for varying periods of time.</li> </ul>
<b>Foot-and-mouth disease</b>	<p>A virus of cows, pigs, sheep, goats, deer, and other animals with cloven hooves. Symptoms in these animals include fever, lameness, and blisters on the feet and mouth. There are seven known types and more than 60 subtypes, and immunity to one type does not protect against others. Considered one of the most contagious, infectious diseases.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> Spreads when susceptible animals come into contact with infected animals, contaminated facilities or vehicles, or drink contaminated water, among other ways. It generally does not infect humans, and is not considered a public health or food safety threat.<sup>a</sup></li> <li>• <b>Location:</b> Found in Africa, South America, Asia, and some parts of Europe.</li> <li>• <b>Consequences:</b> Causes production losses for farmers and ranchers. Cost estimates of an introduction of the disease in the United States are more than \$37 billion.</li> <li>• <b>Countermeasures:</b> Vaccines are available but must be matched to the specific type and subtype of the virus.</li> </ul>

**Appendix I: Diseases Planned for Study at the  
National Bio and Agro-Defense Facility**

Disease	Description
<b>Zoonotic diseases planned for study at NBAF<sup>b</sup></b>	
<b>Crimean-Congo Hemorrhagic fever</b>	<p>A virus transmitted by ticks. Although humans are the main host affected by this virus, cattle, goats, sheep, and hares are also hosts of the virus. Symptoms in humans include headache, high fever, back pain, joint pain, stomach pain, and vomiting. Symptoms may also include jaundice, and in severe cases, changes in mood and sensory perception.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> The virus is transmitted by ticks to humans, as well as to wild and domestic animals, such as cattle, goats, sheep, and hares. Transmission to humans can also occur through contact with blood of infected animals or blood or body fluids of humans infected with the virus.</li> <li>• <b>Location:</b> The disease was first identified in Crimea in 1944 and recognized in the Congo in 1969. The disease has since been identified in other areas of the world, including southern Europe, central Asia, Africa, the Middle East, and the Indian subcontinent.</li> <li>• <b>Consequences:</b> Causes lethal hemorrhagic fever in humans with mortality rates up to 50 percent. No illnesses or deaths seem to be associated with the virus in animals, except those animals used during the research and investigation of human disease.</li> <li>• <b>Countermeasures:</b> A vaccine against the virus has been developed for animals and is used on a small scale in parts of Europe. However, there is no safe and effective vaccine currently available for human use.</li> </ul>
<b>Japanese encephalitis</b>	<p>A virus that can affect pigs, horses, birds, cattle, sheep, dogs, cats, reptiles, amphibians, and humans. Most common symptoms in pigs are stillborn or mummified fetuses. Pigs not pregnant do not typically show signs of infection or experience only mild transient fever. Symptoms in horses, though, include fever, anorexia, lethargy, blindness, coma, and death. Horses that recover may continue to have neurological problems. Most infected people do not have symptoms or have only mild symptoms, but a small percentage of infected people develop inflammation of the brain (encephalitis), with symptoms including sudden onset of headache, high fever, disorientation, coma, tremors, and convulsions. About 20 percent to 30 percent of infected people who develop encephalitis die. About 30 percent to 50 percent of people that survive continue to have neurologic, cognitive, or psychiatric symptoms.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> Transmitted through the bite of infected mosquitoes.</li> <li>• <b>Location:</b> Found throughout Asia and the western Pacific, as far west as Pakistan and as far south as Australia.</li> <li>• <b>Consequences:</b> Causes significant reproductive losses in pigs and encephalitis in horses. It is also a significant public health risk, causing 10,000 to 15,000 human deaths annually.</li> <li>• <b>Countermeasures:</b> Vaccines for animals and humans are available. Treatment in humans is symptomatic, such as rest, fluids, and use of pain relievers and medication to reduce fever and relieve some symptoms.</li> </ul>

**Appendix I: Diseases Planned for Study at the National Bio and Agro-Defense Facility**

Disease	Description
Nipah virus	<p>A virus that causes disease primarily in swine and humans. In a 1999 outbreak in Malaysia and Singapore, the virus caused a relatively mild disease in pigs, but nearly 300 human cases with over 100 deaths were reported. There have been no additional outbreaks in Malaysia or Singapore. However, in 2001, outbreaks occurred in Bangladesh and India, and several outbreaks have occurred since in Bangladesh and India. Symptoms in humans include respiratory illness, fever, headache, encephalitis, neurological damage, coma, and death.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> The hosts are tropical fruit bats. Transmission to humans may occur after direct contact with infected bats, infected pigs, or other infected people. In Malaysia and Singapore, humans were apparently infected only through close contact with infected pigs. No occurrence of person-to-person transmission was reported in this outbreak. Conversely, person-to-person transmission of Nipah virus in Bangladesh and India is regularly reported. Transmission can occur through contact with infected body fluids, such as nasal or respiratory droplets, urine, or blood.</li> <li>• <b>Location:</b> Bangladesh, India, Malaysia, and Singapore. Other countries thought to be at risk include Australia, China, and Philippines.</li> <li>• <b>Consequences:</b> Causes severe respiratory and neurologic disease in swine, high mortality in piglets, as well as mortality in humans ranging from 40 percent to 75 percent.</li> <li>• <b>Countermeasures:</b> No drug therapies or countermeasures exist. Treatment is limited to supportive care.</li> </ul>
Rift Valley fever	<p>An acute, fever-causing virus most commonly observed in domesticated animals (such as cattle, buffalo, sheep, goats, and camels), but which can also infect and kill humans. In cattle, symptoms include weakness, depression, diarrhea, low milk yield, and high abortion rates in pregnant cows. In sheep and goats, symptoms include weakness, depression, vomiting, diarrhea, and abortion rates approaching 100 percent. In humans, symptoms include headache, weakness, light sensitivity, blindness, and death. Less than one percent of cases in humans are fatal.</p> <ul style="list-style-type: none"> <li>• <b>Transmission:</b> Transmission primarily through mosquitos and contact with infected animal tissue or blood.</li> <li>• <b>Location:</b> Generally found in several regions in Africa.</li> <li>• <b>Consequences:</b> Has serious consequences for agriculture as well as public health.</li> <li>• <b>Countermeasures:</b> No specific treatment exists, but two vaccines are available and are commonly used to control it in endemic countries. No vaccine is available for use in the United States.</li> </ul>

Sources: U.S. Department of Agriculture (USDA) and Centers for Disease Control and Prevention | GAO-20-331

Note: Foreign animal diseases are not known to be present in the United States, and some of these diseases are zoonotic (i.e., they can be transmitted between animals and humans).

<sup>a</sup>As we reported in March 2019, foot-and-mouth disease infections in humans are very rare: About 40 cases have been diagnosed since 1921, according to USDA. The disease in humans is generally mild, short-lived, and self-limiting. See GAO, *Foot-and-Mouth Disease: USDA's Efforts to Prepare for a Potential Outbreak Could Be Strengthened*, GAO-19-103 (Washington, D.C.: Mar. 12, 2019).

<sup>b</sup>According to USDA officials in March 2020, USDA has identified research it could conduct on Coronavirus Disease 2019 (COVID-19), and this research can be conducted in its existing facilities. Also, this list of diseases differs from the list included in USDA's strategic vision for NBAF. Specifically, USDA officials told us they added Crimean-Congo Hemorrhagic fever to the list of diseases to be studied, which is a change since the department issued its strategic vision, and, in December 2019, USDA officials told us they may still study the Ebola virus in the future, but this is not definite. USDA officials told us they have continued evaluating the diseases they should be focused on and added Crimean-Congo Hemorrhagic fever as a result of infectious disease threats from May 2019 identified by the Department of Defense. Conversely, USDA officials told us that although the Ebola virus is considered to be an emerging zoonotic disease, it does not pose an imminent threat to livestock, and livestock have not been implicated with outbreaks of the virus. As a result, we did not include Ebola virus in this table.

# Appendix II: Comparison of DHS's and USDA's Plans for the National Bio and Agro-Defense Facility

The Department of Homeland Security (DHS) originally assumed responsibility for owning and operating the National Bio and Agro-Defense Facility (NBAF). However, the U.S. Department of Agriculture will carry out this responsibility instead. There are similarities and differences in the departments' plans for NBAF, as shown in the examples in table 6.

**Table 6: Examples of Similarities and Differences between DHS's and USDA's Plans for the National Bio and Agro-Defense Facility (NBAF)**

Examples	DHS	USDA
<b>NBAF Laboratory Director</b>	DHS planned for the NBAF Laboratory Director to be a DHS employee.	The NBAF Laboratory Director was hired in 2019 and is a USDA employee with the Agricultural Research Service (ARS).
<b>Vision and mission of NBAF science program management</b>	<p>No change has occurred in the vision and mission of the NBAF science program management because of the transfer from DHS to USDA. The vision is to promote science programs aligned with the needs of the U.S. food supply, agricultural economy, animal health, and public health. The mission is to create a management system that lowers barriers to efficient and effective scientific research and testing and empowers scientists to collaborate and to integrate end-to-end research development testing and evaluation.</p> <p>The mission includes four primary performance domains:</p> <ol style="list-style-type: none"> <li>1. Research and development</li> <li>2. Diagnostics</li> <li>3. Emergency response</li> <li>4. Training</li> </ol>	
<b>Staffing levels</b>	In 2017, DHS identified a core staff of 18 persons for the future operation of NBAF whose functions aligned with stand-up activities to be performed, according to the DHS NBAF Program Manager. DHS intended for a contractor to develop a staffing plan for the facility, but this did not occur because of NBAF's proposed transfer to USDA.	USDA plans to have 421 full-time equivalents staffed to NBAF for steady-state years, including 286 for operations and maintenance of the facility, and 135 for the science program. <sup>a</sup>
<b>Use of federal employees versus contractor staff</b>	DHS's plans for scientific staffing included a mixture of federal contract positions, research fellows, trainees, visiting scientists, and collaborators from industry and academia. Plans for scientific and support staffing included a small cadre of federal supervisory staff, with oversight of contract personnel.	USDA plans for scientific staffing to consist primarily of federal government employees complemented by a mixture of research fellows, trainees, visiting scientists, and collaborators from industry and academia where applicable.
<b>Purpose of the Biologics Development Module</b>	No change has occurred in the purpose of the Biologics Development Module—a laboratory at NBAF intended to enhance and expedite the transition of vaccines and other countermeasures from research to commercial viability—because of the transfer from DHS to USDA.	
<b>Operation of the Biologics Development Module</b>	No change has occurred in the overall plans to operate the Biologics Development Module. DHS planned to use a government-owned, contractor-operated business model. In May 2020, USDA stated that it also plans to use the same model for the module.	

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**Appendix II: Comparison of DHS's and USDA's  
Plans for the National Bio and Agro-Defense  
Facility**

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**Plans to collaborate with other  
biocontainment facilities and  
private industry**

No change has occurred to overall plans to collaborate with other biocontainment laboratories within the United States, internationally, and with private industry.

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Source: GAO analysis of U.S. Department of Agriculture (USDA) and draft Department of Homeland Security (DHS) information. | GAO-20-331

<sup>9</sup>A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees, divided by the number of compensable hours applicable to each fiscal year.

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# Appendix III: Approaches USDA Has Used to Help Achieve Its Staffing Plans for the National Bio and Agro-Defense Facility

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This appendix provides information about approaches that the U.S. Department of Agriculture (USDA) has been using to help achieve its staffing plans for the National Bio and Agro-Defense Facility (NBAF). These approaches include the following:

- **Using direct-hire authority.** To hire facilities staff and engineering staff, USDA used the government-wide direct-hire authority available for science, technology, engineering, and math staff. This authority is intended to expedite the hiring process, allowing agencies to make appointments without regard to traditional competitive rating and ranking procedures, among other things. USDA is also using the direct-hire authority included in the fiscal year 2019 appropriations to fill up to 50 positions per year until 2025.<sup>1</sup>
- **Recruiting veterans.** According to USDA officials, the department is using special appointing authorities for veterans and has dedicated human resources staff to promote NBAF and its opportunities to local communities, including the Army installation at Fort Riley, Kansas. The department is also dedicating human resources staff to promote NBAF and its opportunities to veterans and to help veterans assess how they can transfer skills to the federal sector, including to NBAF.
- **Recruiting existing contractor staff.** USDA, in coordination with DHS, approached DHS's construction contractor staff performing facilities-type work—such as work on the heating, cooling, and power generation systems—about opportunities to join USDA as federal employees. Officials said that this approach would help retain specialized skill sets for maintaining and operating NBAF. In February 2020, USDA officials told us that eight contractor staff accepted USDA's offer for employment.
- **Establishing an NBAF science-training program.** USDA's Animal and Plant Health Inspection Service (APHIS) established a graduate training program to replace subject matter experts from the Plum Island Animal Disease Center who do not plan to relocate to NBAF. As of June 2020, 16 graduate students have enrolled in the program. Each student has a documented interest in pursuing a career at NBAF. Their interests span a range of disciplines, from development of novel diagnostic platforms and bioinformatics to evaluating the stability of foreign animal disease viruses in feed ingredients.
- **Identifying opportunities for scientist trainees to collaborate with nonfederal scientists.** USDA's Agricultural Research Service (ARS)

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<sup>1</sup>Consolidated Appropriations Act, 2019, Pub. L. No. 116-6, 133 Stat. 82.

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**Appendix III: Approaches USDA Has Used to  
Help Achieve Its Staffing Plans for the National  
Bio and Agro-Defense Facility**

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is implementing a workforce development plan by identifying and developing collaborative research projects with scientists at universities and research institutes. This plan will serve as a training vehicle for individual scientist trainees. As of December 2019, ARS had 11 trainees.

# Appendix IV: Projected USDA Staffing Levels at the National Bio and Agro-Defense Facility

The U.S. Department of Agriculture (USDA) has developed multi-year projections of staffing levels for operations and maintenance and the science program at the National Bio and Agro-Defense Facility, according to USDA documentation. Staffing levels through fiscal year 2024 represent stand-up activities, and staffing levels from fiscal year 2025 through 2029 represent steady-state activities. The projected staffing level for steady-state years is 421 full-time equivalents.<sup>1</sup> See table 7.

**Table 7: USDA’s Projected Staffing Levels for Operations and Maintenance and for the Science Program at the National Bio and Agro-Defense Facility (NBAF), Fiscal Years 2020-2029**

Fiscal year	Staffing level projections (full-time equivalents) <sup>a</sup>		Total
	Operations and maintenance	Science program	
2020	269	46	315
2021	281	78	359
2022	286	98	384
2023	286	114	400
2024	286	133	419
2025	286	135	421
2026	286	135	421
2027	286	135	421
2028	286	135	421
2029	286	135	421

Source: U.S. Department of Agriculture (USDA). | GAO-20-331

<sup>a</sup>A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees, divided by the number of compensable hours applicable to each fiscal year.

<sup>1</sup>A full-time equivalent is a standard measure of labor that reflects the total number of regular straight-time hours (i.e., not including overtime or holiday hours) worked by employees, divided by the number of compensable hours applicable to each fiscal year.

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# Appendix V: DHS's and USDA's Responsibilities for Collaboration on the National Bio and Agro-Defense Facility

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The Department of Homeland Security (DHS) and U.S. Department of Agriculture (USDA) outlined each department's responsibilities for collaboration on the National Bio and Agro-Defense Facility in a memorandum of understanding finalized in January 2020. These responsibilities include those described in table 8 below.

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**Table 8: DHS's and USDA's Responsibilities for Collaboration on the National Bio and Agro-Defense Facility (NBAF)**

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## **DHS's Science & Technology (S&T) responsibilities**

- Consolidate analyses of risk from intentional threats and associated Research & Development (R&D) support needs in collaboration with DHS components.
- Participate in collaborations with USDA and the intelligence community to assess the collective understanding of adversaries' capabilities.
- Conduct analyses to determine the scope and effect of potential biological events through modeling and simulation studies.
- Establish a mechanism for ongoing collaboration between NBAF and DHS's National Biodefense Analysis and Countermeasures Center (NBACC) to foster the capability to conduct research derived from classified sources.
- Provide subject matter expertise to collaborate on and conduct laboratory work at NBACC, and identify NBACC opportunities that may help accelerate the advancement of countermeasures for emerging and zoonotic diseases.
- Identify and support the collaboration of NBACC's subject matter experts for facility standup and operations.
- Consolidate operational requirements within the research and development needs of DHS components as they relate to the NBAF mission and convey these requirements through participation in the NBAF annual stakeholder and homeland security meetings and knowledge gap workshops.
- Participate as a strategic partner and collaborator in USDA's framework to encourage innovation in the bio and agro-defense sector.
- Maintain a strategic presence at NBAF to support national security priorities related to the NBAF mission that may include
  - a scientific program manager to develop DHS's agricultural defense strategic and tactical research and development plans, manage the DHS agricultural defense countermeasure portfolio, and serve as a liaison to the NBAF director; and
  - a scientific advisor to manage a DHS countermeasure-prototyping program, manage transition of projects to industry partners, and serve as a liaison with NBAF research leaders.
- Participate as a member of NBAF's board of directors.

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## **USDA's responsibilities**

- Provide analysis of unintentional and naturally occurring sources of pathogens and work collaboratively to ensure this information is accurately characterized in risk assessments related to the NBAF mission.
- Contribute to the development, conduct, and evaluation of analyses to determine the scope and impact of biological events related to the NBAF mission in collaboration with DHS components and interagency partners, as appropriate.
- Lead NBAF annual stakeholder meetings, including a meeting focused on homeland security and knowledge gap workshops that facilitate collaboration with DHS S&T as a key stakeholder to inform national security research priorities related to the NBAF mission.
- Provide subject matter expertise to collaborate on and conduct laboratory work to understand characteristics of emerging and zoonotic diseases, such as how the pathogens are transmitted.
- Collaborate with NBACC to develop and maintain relationships with operational personnel to support facility standup and operation, develop protocols and procedures, share information, and evaluate lessons learned.
- Establish a framework and mechanism for DHS S&T to support research, development, testing, or evaluation to further their own mission activities, subject to availability of funding.
- Include DHS S&T as a strategic partner and collaborator in the USDA framework to encourage innovation in the bio and agro-defense sector and expedite development of tools and technologies.

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**Appendix V: DHS's and USDA's  
Responsibilities for Collaboration on the  
National Bio and Agro-Defense Facility**

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- Provide on-site space for two DHS S&T employees to support national security priorities relative to the NBAF mission.
  - Include DHS S&T as a member of NBAF's board of directors.
- 

Source: GAO analysis of Department of Homeland Security (DHS) and U.S. Department of Agriculture (USDA) information. | GAO-20-331

# Appendix VI: Comments from the U.S. Department of Agriculture



United States  
Department of  
Agriculture  
  
Washington, DC  
20250

Steve D. Morris  
Director  
Natural Resources and Environment  
Government Accountability Office  
2635 Century Parkway, Suite 600  
Atlanta, Georgia 30345

JUN 18 2020

Dear Director Morris:

The U.S. Department of Agriculture (USDA) appreciates the opportunity to respond to the U.S. Government Accountability Office (GAO) draft report "National Bio and Agro-Defense Facility: Transfer from DHS to USDA is Ongoing, but Critical Steps Remain, GAO-20-331."

USDA appreciates GAO's recognition of our efforts to plan for and implement a successful transfer of the National Bio and Agro-Defense Facility (NBAF) from the Department of Homeland Security (DHS) and the key practices utilized to facilitate this important endeavor. NBAF will be the premier center of scientific excellence for the study of highly contagious transboundary, emerging, and zoonotic animal diseases that pose a threat to U.S. agriculture, the food supply, and public health. NBAF will replace the aging Plum Island Animal Disease Center (PIADC) and will protect U.S. agriculture by facilitating research, developing animal vaccines, performing diagnostic testing, training researchers and veterinarians to respond to biotreatments, closing capability gaps, and enhancing preparedness and response. Additionally, NBAF will be a unique national security asset that will expand on existing relationships, and establish new critical relationships between Federal departments and agencies, the intelligence community, human biodefense community, universities, stakeholders, and international consortia; these partnerships, in turn, will facilitate the comprehensive survey of existing and emerging biological threats against animal agriculture.

As noted in the GAO draft report, critical steps remain to complete the transfer of NBAF to USDA and to prepare this new facility for operations. USDA is committed to working with our partners at DHS to continue the key practices highlighted throughout the GAO draft report. Our priority remains for a successful transfer and operational stand-up of NBAF, including the successful transfer of the mission from PIADC to NBAF.

The GAO draft report correctly indicates that standup of the Biologics Development Module (BDM) is not a critical path activity for transition of the facility and mission from PIADC. We appreciate the new capabilities and capacities to be afforded by NBAF, including the BDM. USDA is committed to continuing to work with our

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**Appendix VI: Comments from the U.S.  
Department of Agriculture**

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partners and stakeholders to establish the BDM operating model and utilize this new capability to accelerate technology transfer and further enhance the bio and agro-defense sector.

Thank you again for the opportunity to review and respond to the GAO draft report.

Sincerely,



Gregory Ibach  
Under Secretary  
USDA Marketing and Regulatory Programs



Scott Hutchins, Ph.D.  
Deputy Under Secretary  
USDA Research, Education,  
and Economics

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# Appendix VII: GAO Contact and Staff Acknowledgments

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## Staff Acknowledgments

In addition to the contact named above, Thomas Cook (Assistant Director), John Barrett (Analyst in Charge), Peter Beck, Kevin Bray, Mary Denigan-Macauley, Justin Fisher, Stephanie Gaines, Kathryn Godfrey, Tim Guinane, Susanna Kuebler, Cynthia Norris, Sushil Sharma, Kiki Theodoropoulos, and Sarah Veale made key contributions to this report.

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