

IN FOCUS

National Bio and Agro-Defense Facility: Purpose and Status

Congress authorizes and oversees federal agency implementation of agricultural biosecurity and biodefense research. Since Congress first authorized appropriations for the National Bio and Agro-defense Facility (NBAF) in FY2006, the Department of Homeland Security (DHS) and the U.S. Department of Agriculture (USDA) have proposed new management, operations, and research plans for this federal research facility. NBAF aims to allow for research on potentially devastating foreign animal diseases (FADs) that cannot be conducted in existing U.S. facilities. It is planned to become fully operational by December 2022.

Purpose

Homeland Security Presidential Directive 9 (HSPD-9), issued by President George W. Bush in 2004, directed the USDA and DHS to "develop a plan to provide safe, secure, and state-of-the-art agriculture biocontainment laboratories that research and develop diagnostic capabilities for foreign animal and zoonotic diseases." DHS created the NBAF program to carry out this directive.

NBAF MISSION: Provide 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 threaten our nation's food supply, agricultural economy, and public health.—USDA NBAF Plan

The NBAF currently under construction in Manhattan, KS, is to replace the Plum Island Animal Disease Center (PIADC), located off the coast of New York, and serve as a state-of-the-art biocontainment facility for federal research on high-consequence FADs. It is designed to be the first U.S. facility to provide Biosafety Level 4 (BSL-4) laboratories capable of housing large livestock. NBAF is also designed with a specialized facility for transitioning countermeasures (e.g., vaccines, antivirals, and test kits) from research to commercially viable products.

FADs and Zoonotic Disease Background

High-consequence FADs are animal diseases not known to exist in the United States that could cause catastrophic economic damage if they entered the country. Some FADs are *zoonotic diseases*—those that can transmit from animals to people—while others are not.

Federal research on high-consequence FADs involves multiple agencies. Primary agencies include the USDA Agricultural Research Service (ARS) and Animal and Plant Health Inspection Service (APHIS), which conduct work on FADs in accordance with their missions to support and protect American agriculture. This work includes research, testing, diagnostic development, and workforce training. The DHS Science and Technology Directorate also conducts research and collaborates with USDA to bring vaccines and diagnostics through regulatory processes.

Laboratory Research Capabilities

As of 2017, the Government Accountability Office identified eight BSL-4 laboratories registered by federal, private, and academic institutions in the United States. BSL-4 is the highest biocontainment level, and such laboratories permit research on exotic disease agents that pose high risks of aerosol transmission and cause frequently fatal diseases for which no vaccines or specific treatments exist. NBAF is to include a large animal BSL-4 laboratory to permit researchers to study zoonotic diseases requiring such biocontainment, such as Rift Valley Fever and Nipah Virus. These diseases are not permitted to be studied at PIADC, as its maximum biocontainment level is BSL-3. While aspects of these viruses are studied at other BSL-4 laboratories in the United States, NBAF's laboratory is to allow for research in large animal models (e.g., swine and cattle).

In addition to BSL-4 lab space, NBAF is to also have BSL-3 laboratories for research on other high-consequence FADs, including Foot-and-Mouth Disease (FMD). According to USDA, an FMD outbreak in the United States could result in economic losses of \$15 billion to \$100 billion. PIADC is the only U.S. laboratory permitted to work on live FMD virus. In 1948, Congress precluded the conduct of such research on the U.S. mainland except with the express permission of the Secretary of Agriculture (21 U.S.C. §113a). In 2008, Congress required the Secretary to provide DHS a permit to possess live FMD virus on the U.S. mainland at a single facility that succeeds PIADC (Food, Conservation, and Energy Act of 2008 [P.L. 110-246], §7524).

Transition from DHS to USDA

USDA managed PIADC and conducted research there from its establishment in 1954 until 2003, when Congress transferred PIADC management to the newly created DHS (P.L. 107-296, §310). USDA continues to conduct research at the facility. In 2006, DHS announced its intention to establish NBAF as a new facility to replace the outdated PIADC. In 2009, DHS selected Manhattan, KS, from among five candidate locations and began construction.

In its FY2019 Budget Justification, DHS announced that upon completion of NBAF construction and commissioning (expected in May 2021), it would transfer NBAF ownership and management to USDA. The explanatory statement for the FY2018 appropriations (P.L. 115-141) stated that DHS is responsible for completing NBAF construction. In June 2019, DHS and USDA signed a memorandum of agreement (MOA) to establish a transition framework.

According to USDA, ARS will own NBAF, and ARS and APHIS will conduct programs and share operational responsibilities. USDA expects approximately 400 people to work at NBAF, equivalent to current staffing at PIADC.

Schedule, Costs, and Appropriations

The original NBAF schedule, as presented to Congress, proposed finishing construction and commissioning NBAF in FY2010. DHS has extended the proposed schedule several times. DHS expects that NBAF will become fully operational in FY2023—13 years after initial expectations. This has kept PIADC open longer than expected.

Costs to replace PIADC with NBAF include site selection, design, construction, operations, maintenance, and transfer of programs from PIADC to NBAF. DHS projects constructing and commissioning NBAF to cost a total of \$1.25 billion. This cost was fully funded as of FY2015 through a combination of federal appropriations to DHS (\$928 million) and funds from the University of Kansas (\$307 million) and the city of Manhattan, KS (\$5 million).

In light of the transfer, Congress has appropriated funds to USDA for hiring, transferring science programs from PIADC to NBAF, standing up activities, and initial operations and maintenance costs. In FY2018 appropriations (P.L. 115-141) and report language, Congress designated an initial \$7 million for hiring at ARS and for human capital development at APHIS. FY2020 appropriations for USDA (P.L. 116-94) provide \$13.1 million to ARS and \$20.8 million to APHIS for transition, equipment purchases, and science programming. The law requires USDA to submit to Congress a 10-year strategic plan for NBAF operations and research before any funds are obligated above FY2019 levels.

Research Plans

Once NBAF is operational, ARS plans to focus on delivering scientific research and developing countermeasures to protect agriculture and public health from FADs, while APHIS plans to focus on diagnostic testing and workforce training. USDA has identified potential diseases for NBAF research (see text box).

In terms of workforce training, APHIS sponsors the NBAF Scientist Training Program, which financially supports graduate education for students who commit to a federal position at PIADC or NBAF once they complete their degrees. It also sponsors the NBAF Laboratory Technician Training Program for undergraduate students, planned to take place at Kansas State University during summer 2020.

Congressional Interest

Congress may be interested in overseeing how DHS and USDA implement the MOA detailing the NBAF transfer, as well as potential coordination on research priorities between the two departments. Pending legislation on this topic includes S. 2695, which would formalize USDA's management and research responsibilities for NBAF, require coordination with DHS, and require biennial reports to Congress until two years after NBAF becomes fully operational. The Senate Agriculture Committee reported this bill in December 2019.

Additional areas of interest for Congress may include the ongoing construction, equipping, staffing, and operations of NBAF, which Congress could address through appropriations, other legislation, or oversight hearings. USDA planning for continued research and operations may be addressed through the 10-year NBAF strategic plan that Congress has required USDA to submit (P.L. 116-94).

Congress may also be interested in stakeholder concerns about the potential for accidental or intentional release of disease agents from NBAF, a concern that some have raised since the proposal to create NBAF and to site it on the U.S. mainland. Congress may choose to continue to exercise oversight of NBAF safety precautions as well as federal disease response plans. APHIS provides information at its Animal Health Emergency management website, including FAD Preparation and Response Plans for many of the diseases that may be studied at NBAF. Potential responses to accidental or intentional release of disease agents from NBAF include the same measures that would be employed for outbreaks with other causes: surveillance, quarantine, vaccination, stamping out (i.e., depopulating or slaughtering affected livestock), depopulating wild reservoir species, and vector control (e.g., spraying for mosquitoes).

Diseases for Proposed NBAF Research

USDA identified the following FADs as meeting mission requirements for potential NBAF research:

African Swine Fever (ASF). Affects swine. High swine mortality. No available vaccine or countermeasures.

Classical Swine Fever (CSF). Affects swine (wild and domestic). Globally widespread. Improved countermeasures needed.

Contagious Bovine Pleuropneumonia (CBPP). Affects cattle. High cattle mortality. Improved countermeasures needed.

Foot and Mouth Disease (FMD). Affects cloven-hoofed animals (buffalo, camels, cattle, deer, goats, sheep). Strain-specific vaccines available. Improved countermeasures needed.

Hendra Virus (HeV). Zoonotic: affects horses and people. Natural reservoir: flying fox. High human and horse mortality. Horse vaccine available. Improved countermeasures needed.

Japanese Encephalitis (JE) Virus. Zoonotic: affects people, domestic animals, birds, bats, snakes, and frogs. Carriers include domestic pigs and wild birds. Vaccine available. Improved countermeasures needed.

Nipah Virus (NiV). Zoonotic: affects swine and people. Natural reservoir: flying fox. High swine and human mortality. No available treatments or countermeasures.

Rift Valley Fever (RVF). Zoonotic: affects people and cloven-hoofed animals (buffalo, camels, cattle, deer, goats, sheep). High animal and human mortality. No vaccine or treatments available in the United States.

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