Meeting Critical Laboratory Needs For Animal Agriculture Examination of Three Options

Outbreaks of animal disease can have catastrophic repercussions for animal agriculture, the food supply, and public health. Rapid detection, diagnosis and response, as well as development of new vaccines, are central to mitigating the impact of disease outbreaks. The proposed National Bio- and Agro-Defense Facility (NBAF) is a next-generation laboratory for animal disease diagnostics, training, and research that would provide critical core components for defense against foreign animal and zoonotic disease threats, but it will be a major investment with estimated construction costs of \$1.14 billion, as currently designed. This report discusses the laboratory infrastructure needed to effectively address the threat posed by animal and zoonotic diseases and analyzes three options for creating this infrastructure: building NBAF as currently designed, building a scaled-back version of the NBAF, or maintaining current research capabilities at Plum Island Animal Disease Center while leveraging biosafety level-4 large-animal capabilities at foreign laboratories.

nimal agriculture is an estimated \$165 billion enterprise that provides food for the nation, generates livelihood for many Americans, and is a significant contributor to U.S. exports—but it is threatened by outbreaks of foreign animal diseases



Credit: USDA/ Keith Weller

(those that originate outside the United States) and zoonotic diseases (those that can be

National Bio- and Agro-Defense Facility or NBAF, was intended to replace the aging

Biosafety levels refer to specific combinations of work practices, safety equipment, and facilities designed to minimize the exposure of workers and the environment to infectious agents.

Biosafety level 3 is required for work with pathogens that can cause serious infection and may be transmitted by the respiratory route. **Biosafety level 3Ag** denotes work with high consequence pathogens in agricultural animals.

Biosafety level 4 is required for work with pathogens that pose a high risk of life-threatening disease for which there is no vaccine or therapy.

Centers for Disease Control and Prevention Glossary/ http://www.cdc.gov

animals and humans). In 2006, the Department of Homeland Security proposed creating a state-of-the-art facility to conduct research on detecting, diagnosing and treating new and emerging animal diseases. The new facility, called the

transferred between

Plum Island Animal
Disease Center, which is
located off the coast of
Long Island in New
York, and would differ
from other high-containment laboratories
because it would be
capable of conducting
research using large

animals, such as cattle and pigs, and be equipped for work on some of the most contagious biosafety level 3 and 4 pathogens, including the virus that causes foot-and-mouth disease.

As currently designed, the estimated cost of constructing the NBAF at its proposed site is \$1.14 billion. Given current fiscal challenges—including cuts in the Department of Homeland Security's science and technology budget, the general fragility of the national economy, and the collapsed real estate value of the Plum Island property (whose sale was once envisioned as a source of revenue for building the NBAF), this report assesses the need for a national animal disease laboratory and analyzes two options in addition to constructing the NBAF as currently designed: (1) building a scaledback version of the NBAF, or (2) maintaining current research capabilities at Plum Island Animal Disease Center while leveraging biosafety level-4 large animal capabilities at foreign laboratories.

An Effective System to Protect the United States against Animal Diseases

Adequate protection of animal agriculture and public health will require an integrated system of human and physical assets that spans governmental agencies, geography, and many programs and activities. This comprehensive system includes the ability to effectively detect disease outbreaks through surveillance and diagnostics, as well as the capacity to respond and to recover from a disease occurrence. Research and development to better understand diseases of concern, to develop accurate diagnostic tests, and to create appropriate treatments, along with workforce training, are critical elements needed to support such an integrated system.

Laboratory infrastructure underlies all of the elements of an ideal integrated system to address disease threats. To accomplish the goals of such a system, the laboratory infrastructure would need to include facilities at a range of biocontainment levels from biosafety level 1 through biosafety level 4, facilities for laboratory work, and facilities for work in a broad range of laboratory and agricultural animals from mice and rabbits to livestock such as cattle, pigs, and horses.

The Need for High Bio-Containment Facilities in the United States

A substantial number of high-biocontainment laboratories (biosafety level 3 or 4) have been

constructed in the United States over the past 10 years by federal and state agencies, universities, and private companies. These facilities provide an opportunity for collaborations that maximize national efforts to detect and respond to animal and zoonotic disease outbreaks, and could potentially enhance the efficient use of an NBAF.

However, the committee found that despite these expansions, biosafety level 3 laboratories that can accommodate agricultural animals such as cattle and swine are still insufficient to meet all needs for animal disease research, particularly for work with foot-andmouth disease virus, and large-animal biosafety level 3 facilities at Plum Island are dated and increasingly cost-inefficient. Although there are several biosafety level 4 laboratories in the United States, these laboratories do not have the capacity to handle large animals. A small number of such facilities do exist outside the United States, and may be willing to collaborate with U.S. scientists to investigate pathogens that require large animal biocontainment; however, their primary responsibility is to address their own national government and domestic needs. Thus, the committee concludes that it is imperative to build a facility in the United States that is capable of working with agricultural animals at biosafety level 4 containment.

Analysis of Three Laboratory Infrastructure Options

The committee identified the advantages and liabilities of three options for providing a national laboratory infrastructure to address the threats posed by foreign animal diseases and zoonotic diseases.

Option 1: Constructing the National Bio- and Agro-Defense Facility as Currently Designed

As currently designed, the NBAF includes all components of the ideal laboratory infrastructure in a single place, eliminating the need to move specimens or materials to or from other locations, and meets current and anticipated future mission needs of the federal agencies responsible for protecting U.S. agriculture. However, there are substantial costs are associated with the construction, operation, and management of the proposed facility, in addition to the cost of proposed expansions in Department of Homeland Security and United States Department of Agriculture programs. The system does not leverage other existing investments in high biocontainment laboratory, diagnostic, training, and vaccine development in the United States, and therefore could

duplicate these resources. However, the NBAF could function as part of an integrated national strategy that also includes distributed and collaborative partnerships.

Option 2: A National Bio- and Agro-Defense Facility of Reduced Size and Scope

Several components of the NBAF could be reduced in size or scope by developing partnerships with other U.S. and international entities to supplement NBAF capacity. This supplementation could include most critical core components of the proposed facility, except research on foot-and-mouth disease virus and large animal work at large-animal biosafety level 4. Teaching and training could be carried out in collaboration with other U.S. laboratories.

This option would have lower construction costs, and might also have lower sustained operations costs, although the actual cost implications need further examination. This option could still consolidate Department of Homeland Security and United States Department of Agriculture missions and would address critical core gaps in biosafety level 3 and 4 large animal capabilities in the United States. It would also make more efficient use of recently expanded high biocontainment laboratory capacity within the United States. This option requires the United States to implement an integrated system to address animal diseases and to draw on a distributed network of partnerships to fulfill some of the functions required of the system.

Option 3: Maintaining the Plum Island Facility and Leveraging Large-animal biosafety Level 4 Capacity of Other Partners

Plum Island is the only U.S. facility for research, diagnostics and training related to foot-and-mouth disease. However, the facility is aging and there are substantial costs associated with maintaining and operating the facility over the long term. Plum Island does not meet current high standards for high-containment laboratories, and lacks biosafety level 4 facilities.

Although relying on international partners for biosafety level 4 work is a possibility, there is minimal capacity to undertake such work near the United States, and limited capacity in other international laboratories. Agreements with foreign partners and funding for collaborations would be needed, and access to large-animal biosafety level 4 capabilities could be limited in times of critical need. This option

would also separate large-animal biosafety level 4 capabilities from other animal disease research.

The Role of a National Laboratory in an Integrated System

A national role in the coordination of the U.S. disease surveillance and response system is essential, and a central federal laboratory or laboratories would be the cornerstone of an integrated system. As part of the national infrastructure for protecting animal and public health, there is an imperative to build large-animal biosafety level 4 large animal space in the United States. With regard to the three options analyzed, the committee concluded:

- The NBAF as currently proposed includes all components of the ideal laboratory infrastructure in a single location and has been designed to meet current and anticipated future mission needs, but the proposed facility also has drawbacks.
- A partnership of a central national laboratory of reduced scope and size and a distributed laboratory network can effectively protect the United States from foreign animal and zoonotic diseases, potentially realize cost savings, reduce redundancies while making the system of biocontainment laboratories more cohesive. However, the cost implications of reducing the scope and capacity of a central facility cannot be known without further information and study.
- Maintaining the Plum Island Animal Disease Center and leveraging large-animal biosafety level 4 large-animal capacity of other partners would avoid the costs of constructing a new replacement facility. However, the facilities at Plum Island are aging, and do not meet current standards for high-biocontainment laboratories. There are substantial costs associated with maintaining and operating the Plum Island facility over the long term, and it lacks biosafety level 4 and large-animal biosafety level 4 capabilities. Given uncertainties about the priorities of a foreign laboratory in an emergency, it would not be desirable for the United States to rely on international laboratories to meet large-animal biosafety level 4 needs in the long term.

Regardless of the options considered for a central facility, developing and implementing an integrated national strategy would help address foreign animal and zoonotic disease threats. Because foot-and-mouth disease research remains critical for the U.S. animal health system, it will be essential to continue to support the Plum Island facility until an alternative facility is authorized, constructed, commissioned, and approved for work on foot-and-mouth virus.

Additional Considerations for Fulfilling National Needs

- Balanced support for infrastructure and research and development. It is critical for policy-makers and agency planners to recognize that an effective system for addressing foreign animal and zoonotic disease threats consists of more than facilities; it also requires robust research programs.
- Ongoing planning and prioritizing for the national system. Conceptualizing, implementing, and maintaining a national system to address

- threats posed by foreign animal and zoonotic diseases requires not only an understanding of today's priorities and technologies but continued monitoring and assessment to understand how the high-priority threats and the tools available to address them change over time. Such vision and planning are critical and must be ongoing.
- Exploring alternative funding mechanisms to supplement current federal allocations for capital and operational costs and for program support would be useful.
- Considering all factors of concern. To most appropriately fill critical laboratory needs in the United States, all factors of concern (including site location, risk assessment, political considerations, adaptability for the future) will need to be considered in a more comprehensive assessment.

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The National Academies appointed the above committee of experts to address the specific task requested by the U.S. Department of Homeland Security. The members volunteered their time for this activity; their report is peer-reviewed and the final product signed off by both the committee members and the National Academies. This report brief was prepared by the National Research Council based on the committee's report.

For more information, contact the Board on Agriculture and Natural Resources at (202) 334-3062 or visit http://dels.nas.edu/banr. Copies of *Meeting Critical Laboratory Needs for Animal Agriculture: Examination of Three Options* are available from the National Academies Press, 500 Fifth Street, NW, Washington, D.C. 20001; (800) 624-6242; www.nap.edu.

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