



NBAF Update

Secretary's Advisory Committee on Animal Health

September 8, 2016

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*Includes slides provided by the DHS
NBAF Program Executive Office



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NBAF Mission



The NBAF, a new, state-of-the-art biosafety level (BSL) 3 & 4 facility, located in Manhattan, KS, will enable the U.S. to conduct comprehensive research, develop vaccines and anti-virals, and provide enhanced diagnostic and training capabilities to protect our country from numerous foreign animal, emerging and zoonotic diseases to assist in protecting our food supply and the nation's agriculture economy and public health.



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NBAF Drivers

- Homeland Security Presidential Directive 9 (HSPD-9)
 - Establishes a national policy to defend the agriculture and food system against terrorist attacks, major disasters, and other emergencies
 - Paragraph 24: *The Secretaries of [USDA and DHS] will **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.***
- United States has no capacity for large livestock research in BSL4 and is dependent upon use of facilities in other countries.
- Plum Island Animal Disease Center (PIADC) is over 60 years old
 - End of its useful life
 - Limited capability
- Threats are evolving and emerging
 - Over 70% of emerging diseases are zoonotic



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NBAF Project Status

- Facility Design
 - Initiated in March 2007 - Completed in July 2012
- Site Preparation
 - Initiated in November 2010 - Completed August 2012
- Central Utility Plant (CUP)
 - Initiated March 2013 – Completed October 2015
- Main Laboratory Construction
 - Initiated May 2015



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NBAF Site Plan

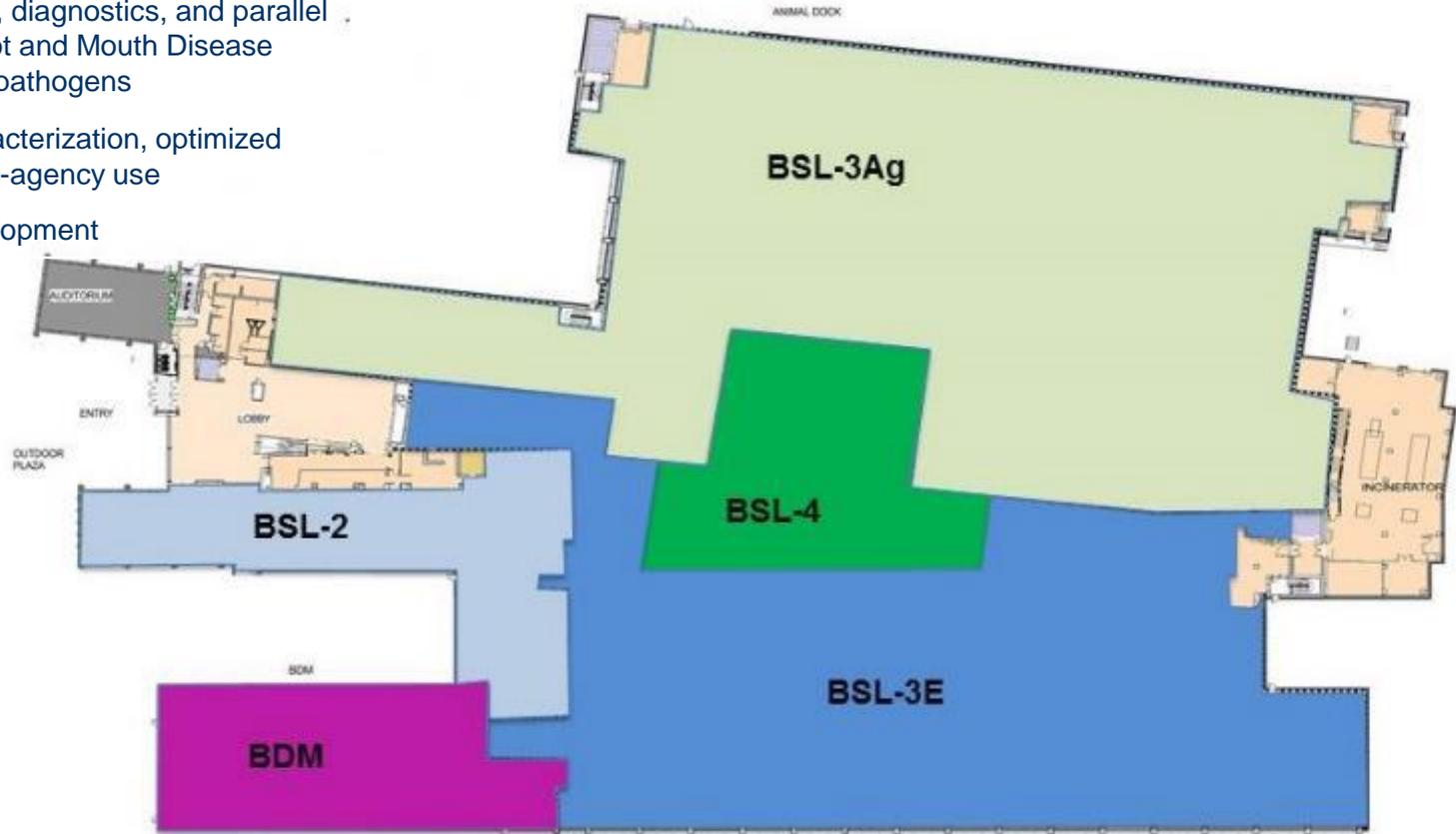


- Completed NBAF site will encompass over **700,000** sq.ft.
- Main lab building provides **574,000** sq.ft. of integrated laboratory space, support areas, and required safety systems.
- Other structures total **135,000** sq.ft.
- The Kansas State University Biosecurity Research Institute (BRI) will be leveraged for training, complementary research, and administration.

The Biotechnology Development Module (BDM), plus the nearby presence of commercial animal pharmaceutical and biopharmaceutical firms, will increase the speed with which new diagnostic tests, vaccines, and medicines are developed, tested, and put into use.

NBAF Laboratory Facility Plan

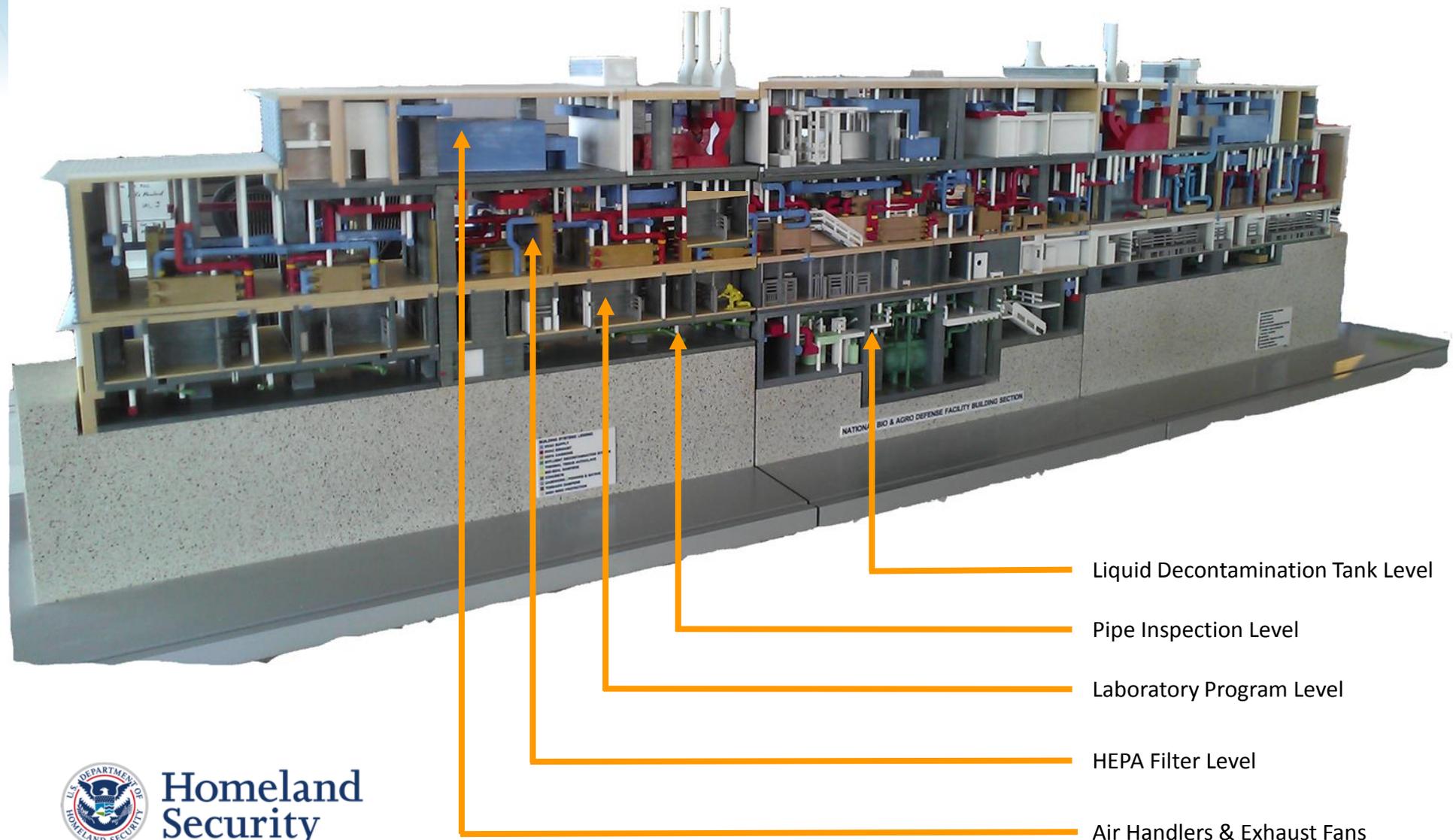
- **BSL-4:** High consequence zoonotic diseases
- **BSL-3E + BSL-3Ag:** Research and Development (R&D), diagnostics, and parallel vaccine trials for Foot and Mouth Disease (FAD) and zoonotic pathogens
- **BSL-2:** Assay, characterization, optimized throughput and multi-agency use
- **BDM:** Vaccine development



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NBAF Laboratory Cross-Section



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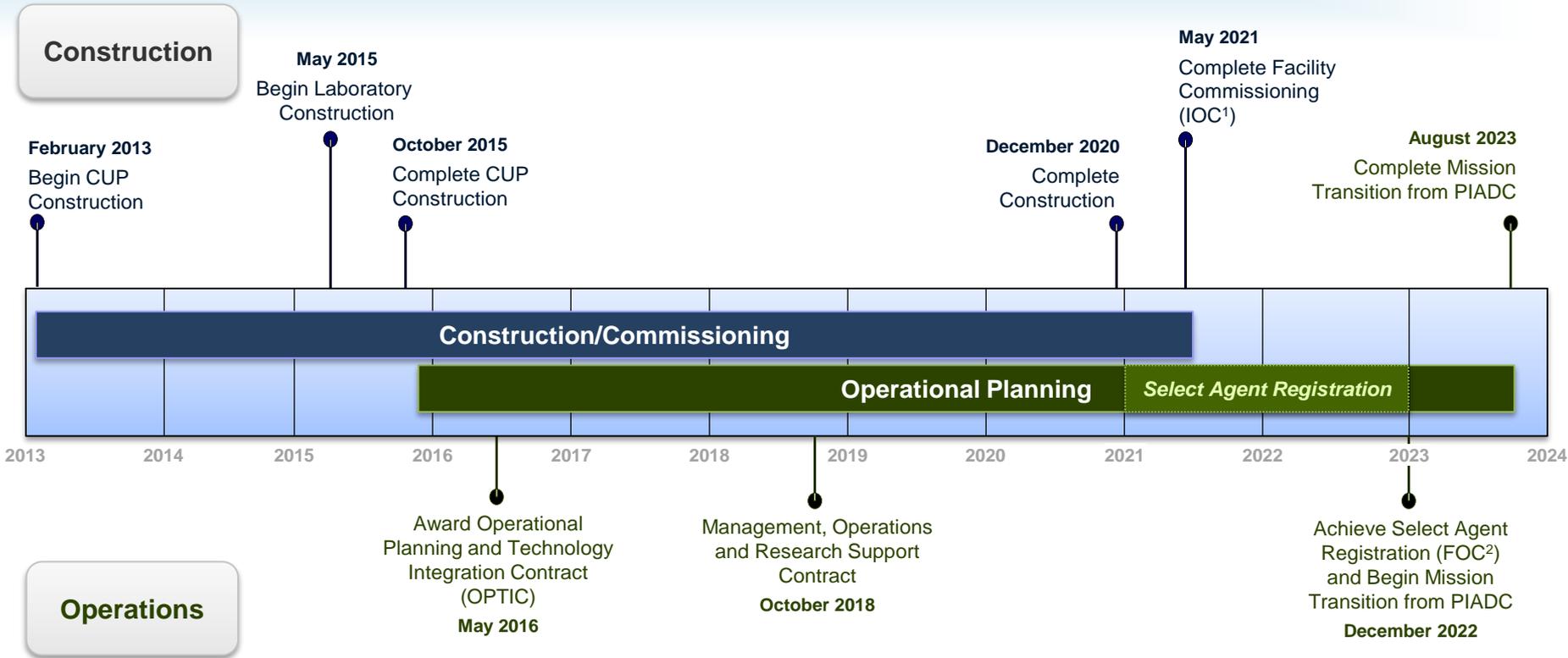








Operations and Transition - NBAF Integrated Project Timeline



Total 400 staff when steady state

¹ Initial Operating Capability

² Full Operating Capability



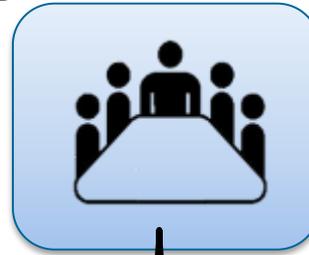
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NBAF Strategic Management Structure

- *Mission: To develop and implement a framework that will drive, integrate, and support strategic partnership initiatives, operational planning activities, and ongoing NBAF construction until the NBAF becomes fully operational in 2022-2023*

Executive Steering Committee (DHS and USDA)

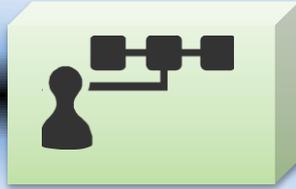


James Johnson (Chair, DHS)
Dr. Beth Lautner (USDA APHIS)
Dr. Steve Kappes (USDA ARS)

Working Groups



Partnership
Development



Operational
Stand-up



Facility
Advisory Team



Research and
Workforce
Development



Budget
Formulation
(Federal only)



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Membership from DHS (including S&T University Programs),
USDA (ARS and APHIS), and Kansas State University

NBAF Research, Development, Test & Evaluation (RDT&E) Capabilities

- Provides a national capability for exotic infectious, vector borne and zoonotic disease research involving large livestock
- Expands the development of countermeasures for multiple FAD and zoonotic diseases; developing, testing, and evaluating novel delivery methods of those product types
- Enhances opportunities for industry engagement in the advanced development pipeline and improve probability of successful technology transitions → *broadened interagency mission*
 - NBAF is in proximity to Kansas State University, the Kansas City Animal Health Corridor, and several agricultural/land grant universities
 - NBAF Biotechnology Development Module (BDM) will enable stronger collaboration with the veterinary biopharmaceutical industry
 - Designed to support the development and eventual license of products/reagents discovered and developed at the NBAF.
 - Envisioned as a collaborative space for engaging industry.
 - Adds cGMP capabilities to the NBAF mission that are not present at PIADC.
 - BSL-4 livestock capability may foster collaborative opportunities with other federal agencies (i.e., DOD, HHS)
 - A capability heretofore unavailable within the U.S.
 - Fosters RDT&E involving emerging infectious threats



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Research – NBAF Core Science Programs

DHS S&T Chem-Bio Defense Agricultural Defense Branch

Mission: To enhance current capabilities and develop state-of-the-art countermeasures for high priority foreign animal diseases. This includes near- and long-term research and development for vaccines and diagnostics, in coordination with internal and external stakeholders.

USDA Agricultural Research Service (ARS), Foreign Animal Disease Research Unit (FADRU) Mission Statement

Mission: Deliver scientific information and veterinary medical countermeasures to prevent, detect, control, and eradicate animal diseases that pose the highest threat to U.S.

USDA Animal and Plant Health Inspection Service (APHIS), Foreign Animal Disease Diagnostic Laboratory (FADDL) Mission Statement

Mission: To protect U.S. livestock from foreign and emerging diseases through early detection and diagnosis and training, and to serve as an international reference laboratory.

NBAF also seeks partnerships with other U.S. government agencies and international laboratories



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NBAF Science Expansion

- The NBAF will include a Biotechnology Development Module (BDM) which will accelerate existing countermeasure development efforts and increase opportunities to partner with industry.
 - The BDM will be capable of vaccine master seed production (pilot scale) and scaling up production of small lots of candidate countermeasures.
 - This new space will allow DHS and USDA researchers to develop countermeasure technologies to a point attractive as an investment to the animal biologics industry.
 - This new capability will allow for additional flexibility in partnering with industry in the advanced development of countermeasures, both through the traditional contracts and cooperative research agreements, as well as the potential to explore non-traditional approaches to collaboration.



BSL-4 Overview

- NBAF will be the first BSL-4 facility in the United States for large animal research on high-consequence zoonotic pathogens in host livestock animals, including emerging zoonotic BSL-4 pathogens
- The BSL-4 animal and laboratory space will be shared between DHS, USDA Agricultural Research Service (ARS), and USDA Animal and Plant Health Inspection Service (APHIS)
- Planned research programs for the BSL-4 space include foreign animal and zoonotic diseases
- With the availability of BSL-4 infrastructure, a mission-directed focus on zoonotic diseases, and co-location within the Kansas City Animal Health Corridor, the NBAF provides a tremendous opportunity for accelerating the translation of laboratory discoveries into solutions for both animal and public health
- BSL-4 space is an opportunity to pursue collaboration with CDC.



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National Veterinary Services Laboratories

“To safeguard U.S. animal health and contribute to public health by ensuring that timely and accurate diagnostic laboratory support is provided directly or by our coordination of the nationwide animal health diagnostic system.”

- Reference and confirmatory laboratory for USDA
- International - World Organization for Animal Health (OIE) reference laboratories and Food and Agriculture Organization (FAO) reference centers
- Ames – located at National Centers for Animal Health (NCAH)
 - Diagnostic Virology Laboratory
 - Diagnostic Bacteriology Laboratory
 - Pathobiology Laboratory
- New York – located at Plum Island Animal Disease Center (PIADC)
 - Foreign Animal Disease Diagnostic Laboratory (FADDL)



APHIS Foreign Animal Disease Diagnostic Laboratory (FADDL) *Science Mission*

- ❑ Test samples from U.S. animals with clinical signs consistent with foreign animal diseases (FADs)
- ❑ Maintain the only FMD Vaccine Bank for North America
- ❑ International capacity building
- ❑ Training of U.S. and international veterinarians and diagnosticians
- ❑ Development of novel assays and diagnostic reagents
- ❑ Safety test animal products and live animals being imported
- ❑ OIE/FAO Rinderpest Holding Facility
- ❑ Serve as a reference laboratory for:
 - U.S. National Animal Health Laboratory Network (NAHLN)
 - United Nations Food and Agriculture Organization (FAO)
 - World Organization for Animal Health (OIE)



APHIS NBAF Diagnostic Enhancements

- Ensure facilities capable of 24-7-365 operations to meet emergency response diagnostic testing needs
- Provide needed capabilities for diagnostic testing of emerging, zoonotic and BSL-4 agents including Nipah, Hendra and Rift Valley fever virus
 - Ability to work with samples of unknown zoonotic potential
 - Ability to move seamlessly from BSL-3 to BSL-4 when risk to laboratory personnel requires this biosafety level
 - Ebola Reston diagnostic case
 - Ability to meet international reference laboratory responsibilities and maintain protection of U.S. from FADs and emerging diseases including zoonotics – currently unable to accept samples from some countries due to known or unknown zoonotic disease risk of situation
- Integrate state-of-the-art high throughput diagnostic testing facility to meet high volume testing needs in outbreaks and to validate assays for NAHLN deployment





APHIS NBAF Diagnostic Enhancements

(continued)

- Establish a robust reagent development program to meet national emergency preparedness needs and international reference laboratory responsibilities
 - Produce reagents if needed in Biotechnology Development Module
 - Expand stockpile of diagnostic reagents
- Expand the FAD diagnostic assay validation and proficiency testing program for the NAHLN
 - The numbers of diseases for which validated assays are needed/required is expected to expand and include both antigen and antibody detection capabilities.
- Expand a FAD diagnostic program for the development and validation of new and emerging technologies
- Enhanced space and specialized facilities to train veterinarians in the recognition of FADs
 - Expand training opportunities without interfering with ongoing science programs

APHIS NBAF Transition

- Serving on various working groups to address transition – leading Workforce Development Working Group
- Stood up APHIS NBAF Transition Team (more than 15 members)
- Looking to start placing positions in Manhattan, KS – hiring flexibilities
- Collaborations with KSU
 - Development of Monoclonal Antibodies Specific to ASFV Proteins (DHS funded)
 - Advanced Molecular Detection Methods for Foreign and Emerging Animal Disease
 - Pen-side Multiplex Detection of FMD and BPS (DHS funded)
 - Summer rotation for KSU veterinary students
- Exploring advanced training opportunities for current FADDL scientists and workforce development
- Staffing to enhance epidemiology and bioinformatics capability and overall capacity to address emerging diseases including One Health

ARS Biodefense Animal Disease Research Program

- **Plum Island Animal Disease Center (BSL-3), Orient Point, NY**
 - Foot and Mouth Disease (FMD) research
 - Classical Swine Fever (CSF) research
 - African Swine Fever (ASF) research
 - Vesicular Stomatitis (VSV) research

- **SEPRL (BSL-3), Athens, Georgia - Poultry diseases**
- **NADC (BSL-3), Ames, Iowa – Emerging animal diseases**
- **ABADRU, Manhattan, Kansas - Vector-borne diseases**



ARS Research Program

Foreign Animal Disease Research Unit

- **The goals of the existing scientific program are to:**
 - **Identify genetic and biological determinants of viral virulence**
 - **Determine the molecular mechanisms of FMDV pathogenesis and persistence**
 - **Develop novel strategies to control FMDV**
 - **Develop methods for rapid control of CSFV and ASFV**

ARS Program of Requirements

- The Program of Requirements for the ARS foreign animal disease research program are to 1) provide solutions to problems associated with disease control, eradication, and recovery and 2) maintain a portfolio of expertise that will allow ARS to rapidly respond to new and unforeseen disease threats.
- Since several foreign animal diseases and/or new emerging diseases cause disease outbreaks worldwide every year, priority setting requires a flexible and rapid system to ensure the scientific program at NBAF can effectively respond to any disease outbreak in the United States.



ARS NBAF Transition

- Conduct comprehensive, science-driven gap analyses
- Establish research programs in Manhattan, Kansas
- Establish strategic international research collaborations
- Train next generation of foreign animal disease scientists

Foot-and-Mouth Disease Gap Analysis

Workshop Report
December 2010



USDA
United States Department of Agriculture
Agricultural Research Service
December 2011

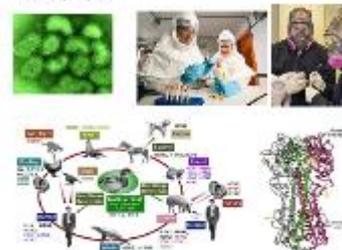
Orbiviruses Gap Analysis Bluetongue and Epizootic Hemorrhagic Disease Workshop Report



USDA
United States Department of Agriculture
Agricultural Research Service
March 2014

Animal Influenza Viruses Gap Analysis

Workshop Report



<http://go.usa.gov/kCqF>

<http://go.usa.gov/BJ5F>

<http://go.usa.gov/KpGP>



Gaps in existing research program that will be addressed in NBAF

- The current research program on vector-borne diseases is insufficient.
- The size of the research program limits the integration of basic and applied research.
- The current program does not include zoonotic diseases. With 70% of new and emerging diseases characterized as zoonoses, significant impact will be achieved if we can control these biological threats in animals, thereby eliminating the source and exposure to people.
- Lack facilities to conduct research on new and emerging zoonotic diseases in farm animals.
- The current program only focuses on four pathogens. Since we do not know what the next emerging disease, exotic disease, or agro terrorist threat will be, the portfolio of expertise must be extensive enough to cover current and future threats.

Priorities and future program expansion

- ❑ Pathogens identified as priority diseases by APHIS and DHS
- ❑ Pathogens that represent different biological types
- ❑ Pathogens within taxonomic families that provide the greatest coverage of expertise, including experience working at a particular biocontainment level, biological type, and agricultural and wild-life animal species
 - *Bunyaviridae (Rift Valley Fever)*
 - *Flaviviridae (Classical Swine Fever)*
 - *Paramyxoviridae (Peste des Petits Ruminants, Classical Swine Fever)*
 - *Picornaviridae (Foot and Mouth Disease)*
 - *Poxviridae (Lumpy Skin Disease)*
 - *Asfarviridae (African Swine Fever)*
 - *Rhabdoviridae (Vesicular Stomatitis)*



Questions for SACAH

- What information about NBAF would the SACAH like to receive as planning and construction continues?
- How would the groups you represent like to receive NBAF updates? What are existing mechanisms we can use?
- How would the SACAH and the groups you represent like to provide input into NBAF's priorities as the programs are developed? After NBAF is operational?

