The Agricultural Defense mission is 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.  

HSPD-9 Paragraph 23: The Secretaries of [DHS, USDA, HHS, EPA...] in consultation with the Director of the Office of Science and Technology Policy, will accelerate and expand development of current and new countermeasures against the intentional introduction or natural occurrence of catastrophic animal, plant, and zoonotic diseases. The Secretary of Homeland Security will coordinate these activities.
S&T’s Agricultural Defense Programs span the entire outbreak spectrum

Agricultural Screening Tools (AST) to verify disease free status so uninfected animals and products can continue to move maintaining business continuity w/in U.S.

Livestock Decontamination, Disposal and Depopulation (3D): New methodologies and decision support tools for depopulation, disposal and decontamination that facilitate rapid response and prevent disease spread in a manner that minimizes waste, environmental impact and negative public perception.

Enhanced Passive Surveillance (EPS) includes diagnostic tests, surveillance tools and data integration procedures to identify infected animals prior to overt symptoms and improve our ability to detect diseases that threaten the U.S. agricultural critical infrastructure.

High throughput diagnostics (DX) allow more rapid confirmation of disease status and increased sample processing capabilities enhancing our ability to contain outbreaks.

Vaccines (VX) to rapidly prevent disease in healthy animals prevents disease spread among healthy herd, maintaining business continuity.

Agricultural Screening Tools (AST) to verify disease free status so uninfected animals and products can continue to move maintaining business continuity w/in U.S.

Diagnostics (DX) to distinguish vaccinated from infected animals may allow more rapid return to trade status, enhancing business continuity and minimizing economic impact.

Livestock Decontamination, Disposal and Depopulation (3D): New methodologies and decision support tools for depopulation, disposal and decontamination that facilitate rapid response and prevent disease spread in a manner that minimizes waste, environmental impact and negative public perception.

Tools to support planning and response, drive requirements for countermeasures development and inform post-outbreak response activities by creating scalable (local to national) simulation and modeling tools to analyze potential responses and control options to minimize FAD spread.
Enhanced Passive Surveillance Project

Objective and Output:
Develop nationwide surveillance capability to for early identification of endemic, transboundary and emerging outbreaks.

• Collect animal health syndromic data from private practitioners
• Integrate multiple surveillance data streams from varied sources in near-real-time
• Determine baseline prevalence rates for observed animal health status reports
• Establish “triggers” to alert officials based on variations in animal health status

2016 Accomplishments:
• Collected 4000+ swine and mixed animal reports in 13 states since September 2015
• Integrated 3174 verified premises locations into the system
• Developed and fielded an improved industry-specific mobile swine application
• Current engagement with poultry, dairy and feedlot industries
• Ongoing data integrity and data security testing

<table>
<thead>
<tr>
<th>Industry</th>
<th>Number enrolled companies</th>
<th>Total number enrolled participants across all companies</th>
<th>Number trained participants submitting for this reporting period</th>
<th>Role of submitter (vet/tech/govt)</th>
<th>Number of requested iPads distributed</th>
<th>Number reports submitted</th>
<th>Type of report (healthy/syndromic)</th>
<th>Number states covered</th>
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<tr>
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<td>6</td>
<td>22</td>
<td>4 (-2)</td>
<td>10/130/0</td>
<td>24</td>
<td>1614 (140)</td>
<td>140/0</td>
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<tr>
<td>Mixed Animal</td>
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<td>77</td>
<td>14 (4)</td>
<td>254/0/6</td>
<td>71</td>
<td>2196 (331)</td>
<td>214/117</td>
<td>4</td>
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<tr>
<td>Total</td>
<td>6</td>
<td>99</td>
<td>18 (2)</td>
<td>264/130/6</td>
<td>95</td>
<td>3810 (471)</td>
<td>354/117</td>
<td>13</td>
</tr>
</tbody>
</table>
Detailed assessment of veterinary diagnostic laboratory system capabilities and develop a recommended strategy for integrating AgConnect® with USDA NAHLN laboratory information management systems and/or test result reporting mechanisms.

Enhance the existing epidemiological and emergency response capabilities of the AgConnect® system.

Investigate potential future expansion/integration with public health surveillance systems
- Includes DHS S&T Real-time Biothreat Awareness Apex program

Continue development of a transition plan for AgConnect® to the commercial marketplace

Performer: Institute for Infectious Animal Diseases, end date: 3/26/2018
FAD Vaccines and Diagnostics Project

FMD Vaccines (initiated 2005)

- Near term - Import permits for ‘Off the shelf’ foreign-manufactured, inactivated FMD vaccines *Import permit July 2011
- Mid term - New serotype- and subtype-specific, marked, molecular vaccines (pipeline) *Conditional License May 2012; Renewed May 2014 & 2016
- Long term - Broad spectrum countermeasures: multi/panvalent vaccines, biotherapeutics and immunomodulators *Ongoing Projects

Countermeasures for Other FAD
- Prioritized agents identified by key customer (USDA-APHIS Emergency Management – NVS) and interagency working groups (FADT)
- Includes near term, mid term and long term R&D funding projects for African Swine Fever and Classical Swine Fever

Diagnostics
- DIVA companion assays for vaccines in development

2016 Accomplishments
- Three additional master seeds for the Ad5-FMD vaccine (#6-8) CVB Approved
- Commercial partner showed >50% reduction in commercial production costs using two master seeds of the Ad5-FMD vaccine (#2 & #3)
- Initiated assessment of broad spectrum countermeasure alternatives for emerging diseases
- Initiated POC studies for multivalent FMD vaccine(s)
Agricultural Screening Tools Project

Objective: Development of portable tools and standardized protocols to provide rapid detection and field identification of high priority pathogens and toxins of concern in the U.S. livestock and agricultural sector.

Outcome: Tools to facilitate decisions on animal movement to preserve continuity of business.

Ongoing Awards
- Multiplex High-Sensitivity Detection of APHIS High Consequence Diseases on a Mobile Platform, MRI Global (D15P00218)
- Rapid, low-cost, field-deployable diagnostic device for viral infectious diseases in animals, University of Tennessee
- Pen-side multiplex detection of foot-and-mouth disease virus and bovine papular stomatitis virus by a portable microfluidics PCR system for rapid clinical disease differentiation, Texas A&M Agrilife
Multiagency effort to develop new and enhanced:

- methodologies and equipment for high-capacity mass livestock mortality depopulation and disposal;
- decision support tools for FAD mass livestock mortality disposal;
- strategies for depopulation best management practices and for cleaning and disinfection of animal facilities

2016 Accomplishments:

- Gate Decontamination project completed (IIAD)
- Robotic arms for Portable Vehicle Wash Tunnel – undercarriage and animal carrier units in development (IS4S)
  - 2017 year long demonstration of Wash Tunnel in Huntsville, AL starting mid-October
  - Cold Weather Wash Tunnel Demonstration – TBD
  - 2 Robotics demonstrations - TBD
- Porous surface decontamination project concluded (EPA)
FAD Modeling

Develop and improve FAD modeling tools to support customer (USDA) planning and response to a FAD outbreak and drive requirements for countermeasures development

- **U.S. Animal Movement Model Data Visualization Tool**
  - Online visualization of cattle movement within the U.S.
  - Estimates county-to-county cattle shipments based on movement data
  - Users can download map & supporting data

- **CADENCE: A “What-If?” Tool for Emergency Planners**
  - Animal disease outbreak decision-support tool for emergency responders
  - Multiple scenarios based on animal production type & disease characteristics
  - Provides downloadable outcomes based on user decisions

- **SONATA & SYMPHONY**
  - Animal disease outbreak decision-support tool for emergency responders
  - Multiple scenarios based on animal production type & disease characteristics
  - Provides downloadable outcomes based on user decisions

- **Pre-Harvest Agroterrorism Risk Model (PHARM)**
Objectives:
- Demonstrate effectiveness of Ad5 vectored, multivalent developmental vaccine in an outbreak and/or endemic situation
  - Critical to establishing efficacy and promoting commercial potential.
- Demonstrate process for using vaccine and companion Differentiating Infected from Vaccinated Animals (DIVA) diagnostic in a disease situation
- Build international partnerships to facilitate future trials in endemic settings

Accomplishments:
- Project working groups have reevaluated and revised all of the recommendations made at the June 2014 workshop.
- Top study design preference is cluster randomized trial
- Baseline epidemiologic study in partner country prior to the field trial to further inform study design
- Finalized the criteria for country selection and developed a country outreach strategy.
- Expression of interest solicitation for potential partner countries.
NBAF Training and Workforce Development

- Two, three-year awards (September 2015 – August 2018)
  
  1) Transboundary Animal Disease (TAD) Workforce Development: Fellowship Training Program, Kansas State University (KSU) (D15P00276)
  
  - Two-year fellowship designed to foster the development of research scientists to safely conduct research on TAD in BSL-3, BSL-3Ag, and BSL-4 environments.
  - 18 credit hour High-Containment Agricultural Research program at KSU
  - In the final year, fellows will complete an independent research project under the guidance of an established researcher in the field of TADs.
  - BSL-4 simulator training at the National Emerging Infectious Diseases Laboratory.

  [http://www.bri.k-state.edu/education/TADFellowship.html](http://www.bri.k-state.edu/education/TADFellowship.html)
NBAF Training and Workforce Development

- Two, three-year awards (September 2015 – August 2018)

  (2) From Bench to the Shop: Creation & Implementation of a Scientific Business Development & Management Program to transition High Consequence Disease Research and Development Technologies for Commercialization, Texas A&M Agrilife Research (D15P00280)

  - Online Curriculum
    - Bench: Developing a Strategic Plan of Work - fundamentals of regulations involved in working with pathogens in a high containment laboratory environment and how to apply project management principles to ensure success of basic R&D efforts.
    - Technology Transition: Biological Product and Component Validation - good manufacturing practices (GMP)/ good laboratory practices (GLP), identify industry partners, intellectual property (patents, invention disclosure), process expansion and new technology, and quality control.
    - Business: Transition of a Transboundary Animal Disease R&D Product - building partnerships with businesses, the regulatory environment, risk assessment, creating capitalization plans, intellectual property in the marketplace, entrepreneurship, organizing business models/plans, and business timelines.

  - Experiential Training
    - From the Bench to the Shop: Technology Transition to the Global Marketplace - 3-week experiential short course focused on vaccines, diagnostics, therapeutics, and biologically relevant specimens, includes biocontainment experience.

http://vetmed.tamu.edu/benchtoshop
In addition to traditional contractual relationships, the Ag Defense Branch works closely with the Plum Island Animal Disease Center (PIADC) and the two Zoonotic and Animal Disease DHS University Centers of Excellence (COEs). Each partner plays a key role in the development process. PIADC develops industry partnerships and conducts critical applied research related to vaccines and diagnostics.

The COEs (i.e., IIAD and CEEZAD) maintain important international, state, local and academic partnerships, and conduct basic research vital to a continuous pipeline of candidates for advanced development and transition.
Working with S&T

- Contact **DHS S&T**: Phone: 202-254-6006; email: SandT@dhs.gov

- **www.fedbizopps.gov**: Posts DHS S&T and all U.S. Government business opportunities

- **https://baa2.st.dhs.gov**: Solicitations Portal for **Broad Agency Announcements**, that address needs of DHS S&T technical divisions

- **https://sbir2.st.dhs.gov**: **SBIR Program** for Small Businesses posts two solicitations annually seeking technical capabilities that cut across DHS S&T divisions

- **http://www.dhs.gov/do-business-dhs**: Provides information on how to work with DHS in general, including information on contracting with the federal government

- **www.grants.gov**: Assists applicants in finding and applying for federal grants
Agricultural Screening Tools Project

Objective: Development of portable tools and standardized protocols to provide rapid detection and field identification of high priority pathogens and toxins of concern in the U.S. livestock and agricultural sector

- Workshop based approach to gather industry, state, local, and federal stakeholders to develop concept of operations and screening priorities
  - Optimization and validation of PCR based testing for FMD in bulk milk samples and multiplex assay for endemic and FAD in oral fluid samples
  - FMD ELISA kits for deployment to the NAHLN
  - Infrared Thermography
  - Comparison and validation of new sample matrices (oral fluids, nasal swabs, blood) for detection of CSF

To facilitate decisions on animal movement to preserve continuity of business
International FMD Vaccine and Diagnostic Trial

Tasks

1 - Workshop(s) to identify partner countries and detailed plan for case-control study and validating 3B DIVA diagnostic assay in endemic countries
2 - Production of additional master seed viruses needed for the bi- or tri-valent vaccine

Procurement of required vaccine and diagnostic kits

If vaccine efficacious at 6 months, continue study to 12 and 18 mo. time points to obtain information related to duration of immunity, effect of boosting, and serological response to vaccine

Future possibility of additional trials with African or Classical Swine Fever vaccines, or additional FMD vector platforms in other countries

Year 1
 Begin in country planning for vaccine trial

Year 2
 Begin field study, initial study period of 6 months

Year 3

Year 4
 Analysis of data and final report
Vaccine and Diagnostic Trial Approach

- A series of meetings/workshops to establish a common understanding of DHS goals and objectives
- Discuss logistical considerations and how to best succeed at the execution of an international with Adenovirus Vectored vaccine and the companion 3B ELISA (short term)
- Establish general recommendations for international field trials
- Identify potential field trial locations and partners for current and future collaborations (Notice of Intent to CRADA)
- Release an “Expression of Interest” for potential partners to respond to once the study requirements and design are established
Project Progress to Date

- Defining Requirements for International Field Trials for Conventional and Next-Generation Foot and Mouth Disease Virus (FMDV) Vaccines and Diagnostics
  - Washington, DC June 10-12th, 2014

- The project working groups have reevaluated all of the recommendations made at the workshop and made revisions where necessary.

- Preference for a cluster randomized trial and baseline epidemiologic study in partner country prior to the field trial to better inform the study design.

- Finalized the criteria for country selection and developed a country outreach strategy. Also, developing the expression of interest to go to partner countries.

- Starting to work through regulatory requirements but will need more input when a partner country is selected.