DHS S&T Funded Efforts in Transboundary Animal Diseases

Presented to the USAHA Foreign and Emerging Diseases Committee

23 October 2012

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Branch Chief, Agricultural Defense
Chemical and Biological Defense Division
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Science and Technology Directorate
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Intra-DHS Coordination

DHS Components participate in Food/Ag subIPT
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.
DHS – Lead the unified national effort to secure America... protect against and respond to threats and hazards to the Nation

✓ S&T: RDT&E to Support DHS Mission

USDA - Provide leadership on food, agriculture... based on sound public policy, the best available science, and efficient management

✓ Strategic Objectives for U.S. Agriculture:
  - Enhance International Competitiveness
  - Enhance Protection and Safety

HSA of 2002; HSPD 5, 7, 9

ESF 11; HSPD 9 - NVS

PIADC

To Protect U.S. Agriculture from the threat of FADs

Programs

✓ USDA APHIS FADDL – FAD diagnostics, NAHLN reference lab, FAD training, NAFMDVB

✓ USDA ARS FADRU – Generates scientific knowledge for FAD prevention, control and recovery - basic research, rapid diagnostics, countermeasures

✓ DHS S&T – Translational product development of countermeasure discoveries for FAD

Operations

✓ Provide outstanding service to science

✓ Protect people, property and the environment

✓ Be a trusted and valued employer and neighbor
FAD Vaccines and Diagnostics Project

- **FMD Vaccines (initiated 2005)**
  - Near term - Enhanced characterization of current vaccine antigens (N. American FMD Vaccine Bank) and commercial FMD vaccines
  - Mid term – Enhanced characterization and import permits for ‘Off the shelf’ foreign-manufactured, inactivated FMD vaccines
  - Long term - New serotype- and subtype-specific, marked, molecular vaccines (pipeline)

- **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 swine (CSF, ASF) and zoonotic (RVF) FADs

- **Diagnostics**
  - Next-generation high-throughput and molecular-based technologies for surge in National Animal Health Laboratory Network (NAHLN)
Import Permits for Foreign Manufactured Vaccines

- Transboundary Animal Biologics, Inc. - a not-for-profit company based in Ames, Iowa established in 2008 and funded by DHS S&T to secure USDA licenses/permits for FAD vaccines and diagnostics
- Bioaftogen is a quadravalent FMD vaccine manufactured by Biogenesis in Argentina
  - Covers the serotypes of FMD found in South America (A24 Cruzeiro, A2001 Argentina, C3 Indaial, and O1 Campos)
  - Permit for sale and distribution in the U.S. issued to TABI by USDA CVB on July 6, 2011 (to be used only under the direction of USDA)
Adenovectored FMD Vaccine

- Conditional license granted for use in cattle on May 31, 2012
- Single serotype - monovalent
- Public-private partnership between DHS, USDA and industry
- Replication deficient viral vector
- Does not contain full FMDv genome, so can be produced within the U.S.
- Planning ongoing for additional studies – other species, duration of immunity, etc. as per needs of industry and USDA
Major Technical Accomplishments (FY11-12)
Other FMD Vaccines

FMD Molecular Vaccines – Adenovirus-based
Pipeline Vaccines for Other Serotype/Subtypes
• Vaccine candidates ready for master seed (8); ongoing testing (2); ready for testing (4)
• Contract in place for additional vector construction – ongoing and as needed
• Manufacturing process improvement studies in progress to reduce cost of goods

FMD Molecular Vaccines – Recombinant, Subunit Platforms
• Plant-based expression platform
• Baculovirus-expression platform
• Prokaryotic expression platform
• Additional investments pending in other platforms - viral-vectored
Technical Approach: Additional FAD Countermeasures

Classical Swine Fever
• Lead candidate discovered by USDA ARS in early-stage regulatory development with Animal Health company (CRADA)

Rift Valley Fever
• First generation vaccine candidate in late-stage regulatory development by animal health company
• Second generation vaccine candidate (DIVA) in partnership with DoD

African Swine Fever
• Live, attenuated and recombinant, subunit approaches through IAA (USDA ARS PIADC) and DHS Targeted BAA non-PIADC performers

Henipavirus (Nipah, Hendra)
• Interest in strategic partnerships for viral-vectored and recombinant, subunit vaccine candidates
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
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
# 3D: Research Approaches

## DEPOPULATION

<table>
<thead>
<tr>
<th>Swine CO2</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1.png" alt="Image" /></td>
</tr>
<tr>
<td><strong>8 TIMES FASTER</strong></td>
</tr>
<tr>
<td>Than euthanizing individual animals in pens and moving to vehicle</td>
</tr>
<tr>
<td>Transition manufacturing specs to responders via published literature and listserv.</td>
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</tbody>
</table>

## DISPOSAL

<table>
<thead>
<tr>
<th>Logistical Infrastructure</th>
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<tbody>
<tr>
<td><img src="image2.png" alt="Image" /></td>
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<tr>
<td><strong>INCREASE CAPACITY</strong></td>
</tr>
<tr>
<td>By developing biosecurity standards for interstate transport</td>
</tr>
<tr>
<td>Transition consensus standards to policy-makers for revised regulations</td>
</tr>
</tbody>
</table>

## DECONTAMINATION

<table>
<thead>
<tr>
<th>Vehicle Wash Tunnel</th>
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<tbody>
<tr>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td><strong>87% Faster, 97% Cheaper</strong></td>
</tr>
<tr>
<td>Than manual pressure washing by hazmat crews</td>
</tr>
<tr>
<td>Transition tested manufacturing specs to manufacturer for marketing</td>
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Needs identified by responders who are part of project team.
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

- Address priority knowledge and capability gaps
  - Planning – What are most effective stop-movement and vaccine strategies for stopping spread? What are cost benefits for each strategy?
  - Diagnose – What are vaccine sensitivity and specificity requirements?
  - Respond – How effective of various vaccine and movement plans?
  - Recover - What are resources needed to implement recovery?

- Develop Next Generation modeling tools
- Enhance inter-agency coordination
- Collect critical data – e.g. livestock transportation
- Recruit and support next generation expertise

FAD modeling is an inter-agency priority
# Doing Business with DHS S&T

<table>
<thead>
<tr>
<th>TYPE</th>
<th>GRANT</th>
<th>CONTRACT</th>
<th>CRADA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Funding</td>
<td>Advance payment allowed if appropriate</td>
<td>Pay for delivery after receipt</td>
<td>No funding from gov’t to collaborator, but collaborator can provide funding to gov’t</td>
</tr>
<tr>
<td>Competition</td>
<td>Competed based on technical/programmatic merits</td>
<td>Price must be considered, technical/programmatic merits considered as well</td>
<td>Agency may put out Notice of CRADA intent, or either party can approach the other to initiate</td>
</tr>
<tr>
<td>Termination</td>
<td>Grantee can terminate</td>
<td>No contractor right to terminate</td>
<td>Either party can terminate</td>
</tr>
<tr>
<td>Deliverable</td>
<td>Publication, report or completion of a project</td>
<td>Product or service required</td>
<td>Products or services agreed to on both sides</td>
</tr>
<tr>
<td>Legal Authority</td>
<td>OMB Circulars</td>
<td>Federal Acquisition Regulation</td>
<td>15 USC 3710a</td>
</tr>
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</table>
Do Business with DHS

Start here if you want to learn about how to work with DHS, how we assist small business, our policies and regulations and business opportunities.

CPO Strategic Plan for FY 2012 - 2014
Learn how the Chief Procurement Officer drives business performance and continuous improvement through the 4 priorities, 30 initiatives and 60 metrics outlined in the FY 2012-2014 Strategic Plan.

Acquisition Policies & Regulations
Get Information on the Department of Homeland Security acquisition policies, regulations, forms and other resources.

Business Contacts
Find the right contact for information on contracts and doing business with the Department of Homeland Security.

Business Initiatives
Learn about the Department of Homeland Security programs to encourage businesses to provide a wide range of programs and services.

Contract Opportunities
Current contracting opportunities, forecasts of contract opportunities, specialized science and technology opportunities and FedBizOpps justification and approval documents.

Get Started: DHS Contracting
Resources for contracting with DHS, including getting started, finding opportunities, mentoring and verifying staff employment eligibility.

Grant Funding
Grants to states, local, and tribal, and regional areas to prepare, prevent and respond to disasters and terrorist attacks.

Small Business Assistance
DHS small business assistance helps companies have fair opportunities to compete and be selected for contracts. Learn about vendor outreach and resources.

The Recovery Act
Funds made the country safe and more secure. Created and saved jobs of people working to prevent terrorism.

http://www.dhs.gov/do-business-dhs
Master Seed (MS) and Working Seed (WS) Lots for Foot-and-Mouth Disease (FMD) Molecular Vaccine Countermeasures

Solicitation Number: HSHQDC-12-R-00081
Agency: Department of Homeland Security
Office: Office of the Chief Procurement Officer
Location: Office of Procurement Operations

Solicitation Number: HSHQDC-12-R-00081 Notice Type: Solicitation

Synopsis:
Added: May 15, 2012 4:40 pm  Modified: Aug 14, 2012 2:50 pm

Request for Proposals (RFP) for acquisition of Master Seed Virus (MSV) and Working Seed Virus (WSV) Lots for Foot-and-Mouth Disease (FMD) Molecular Vaccine Countermeasure.

**This RFP is a Total Small-Business Set-Aside.**

Added: Aug 21, 2012 2:50 pm

RFP Amendment to address industry questions:
1. Is it correct to assume that all 9 of the FMD serotypes to be produced as master seeds will be provided, fully constructed, with details on source of genetic materials and the already-accomplished steps in construction of the pre-master seed viruses be provided for incorporation into the required SIFs?
   - Yes, that is correct.
CHEMICAL AND BIOLOGICAL DIVISION

- **CBD.01** – The Chemical and Biological Division performs analyses and countermeasures, including improved characterization and prioritization of threats, innovative or revolutionary methods for surveillance and detection for early attack warning that minimize exposure and speed treatment of victims, new chemical and microbial forensic methods to support attribution, and novel concepts for decontamination and restoration, agro-defense, and food defense. It is important to note that the division does not fund research on human clinical applications.

- [https://baa2.st.dhs.gov](https://baa2.st.dhs.gov)

- Calendar year cycle
AREAS OF STRATEGIC INTEREST FOR CHEMICAL AND BIOLOGICAL THREATS (additional detail in LRBAA posting):

- **CBD.02** – Improved Sampling (biological particle capture, sample collection from various surface types, and extraction from matrices (e.g. air, water, soil).
- **CBD.03** – Sample Preparation (improving the ratio of analyte of interest to background contaminant (AoI:BC) for chemical and/or biological threats; improving sample processing efficacy to support detection chemistry as appropriate)
- **CBD.04** – Instruments and Detection: Development, prototyping, and improvement of technology and systems which are capable of detecting chemical and biological weapons, etc to support rapid detection and identification immediately after it release.
AREAS OF STRATEGIC INTEREST FOR CHEMICAL AND BIOLOGICAL THREATS (additional detail in LRBAA posting):

- **CBD.05** – Facility protection: Integration of sensors into building systems (e.g. HVAC, Security) and development of associated Concepts of Operations to enable rapid and adaptive responses to chemical and biological releases in order to protect occupants and mitigate the impact of the release.

- **CBD.06** – Prototype and pilot demonstration applications related to sharing of WMD sensor data and related information at the state, local, and federal level utilizing open standards and protocols.

- **CBD.07** – Research and development of next generation and novel methodological approaches to terrorism risk analysis, intentional attack analysis, scenario modeling, and simulation to support risk management, cost benefit analysis, resource allocation, development of mitigation strategies and behavioral modeling.
AREAS OF STRATEGIC INTEREST FOR AGRO DEFENSE
(additional detail in LRBAA posting)

- **CBD.08** – New, cost-effective, biological-based countermeasures for foreign animal disease (FAD) and zoonotic pathogens affecting major domestic livestock species.
- **CBD.09** – New or improved rapid diagnostic tests that facilitate foreign animal disease (FAD) outbreak surveillance, response, and recovery in livestock.
- **CBD.10** – Efforts that address the conceptual design and implementation strategies for a scalable architecture for modeling and analysis of foreign animal diseases for high priority pathogens (at regional and national scales).
- **CBD.11** – New or improved mass animal depopulation methods; facility, personnel, equipment, and material decontamination protocols; and environmentally-sound disposal tools and techniques for animal disease outbreak response and recovery.
DHS S&T Office of University Programs (OUP) awards research and education assistance awards [www.hsuniversityprograms.org](http://www.hsuniversityprograms.org)

**Education Grants:**

- [Career Development Grants](#) - Competitively awarded to accredited universities in the U.S. to provide financial support to students interested in HS-STEM related research and careers. [www.grants.gov](http://www.grants.gov)
- [Summer Internships](#) - Provided to rising juniors and seniors for up to 10 weeks during the summer to conduct research in DHS mission-relevant research areas. [http://www.orau.gov/dhsinternships/](http://www.orau.gov/dhsinternships/)
- [Minority Serving Institutions (MSI) Grants and Awards](#) encourage partnerships with DHS S&T COEs. [www.hsuniversityprograms.org](http://www.hsuniversityprograms.org)
- [MSI Summer Research Team Project grants](#) fund research opportunities at DHS S&T COEs that increase and enhance the scientific leadership at MSIs in DHS-relevant research areas. [http://www.orau.gov/dhsfaculty/](http://www.orau.gov/dhsfaculty/)
- [Scientific Leadership Awards (SLA)](#) fund the development of HS-STEM teaching initiatives, curriculums, and scholarships at MSIs. [www.grants.gov](http://www.grants.gov)

**Centers of Excellence (COE) research awards:**

DHS S&T International Cooperative Programs Office Grants

- International research projects aligned with the mission and requirements of the directorate and designed to augment and complement, through international research and collaboration, the depth and breadth of homeland security science and technology research. [www.grants.gov](http://www.grants.gov)

- Grants.gov: Assists applicants in finding and applying for federal grants ([www.grants.gov](http://www.grants.gov)).
CRADA Characteristics

- The government may contribute a wide variety of resources (personnel, services, facilities, equipment, intellectual property) but NO FUNDS!
- The non-federal partner may contribute FUNDS as well as the wide variety of resources shown above.
- Gives special consideration to small businesses, consortia involving small business, and business located in the U.S. that agree to manufacture products resulting from the CRADA substantially within the U.S.
- Provides the government the ability to retain a nonexclusive, nontransferable, irrevocable, paid-up license to inventions developed under the CRADA.
- CRADAs are sensitive to the needs of business organizations to protect commercially valuable information. Privileged information that develop during the course of a CRADA can be protected from disclosure for up to 5 years.
DHS CRADA Process

- Statement of Work developed between Principal Investigator (PI) and partner
- Completion of CRADA template by PI
- Provide to Technology Transfer Program Manager (PM)
- Review by Technology Transfer PM
- Review by Office of General Counsel (OGC)
- Any negotiations between OGC and partner counsel
- Signature by partner
- Signature by DHS
Key Webpages: Working with S&T

- **Contact DHS S&T** - Phone: 202-254-6006; email: SandT@dhs.gov
- [www.fedbizopps.gov](http://www.fedbizopps.gov) - Posts DHS S&T and all U.S. government business opportunities
- [https://baa2.st.dhs.gov](https://baa2.st.dhs.gov) - Solicitations Portal for Broad Agency Announcements, including the Long Range Broad Agency Announcement, that address needs of DHS S&T technical divisions
- [https://sbir2.st.dhs.gov](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](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.