

FAZD CENTER

NATIONAL CENTER FOR FOREIGN ANIMAL
AND ZOOBOTIC DISEASE DEFENSE

Recommendations for Establishing Policies and Concepts of Operations for Use of Agricultural Screening Tools in a Disease Outbreak

Report from the Agricultural Screening Tools
Workshop III.

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Des Moines, Iowa

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Summary

The Department of Homeland Security (DHS) National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center) convened an agricultural screening tools workshop on October 25-26, 2011, in Des Moines, Iowa. The overall goal of the workshop was to gather input from scientific experts, regulatory officials, and stakeholder groups in preparation for drafting policies related to the diagnosis of, and laboratory response to, foreign animal disease (FAD) outbreaks. Specifically, workshop participants provided input for policies about the use of agricultural screening tools and for laboratory concepts of operations.

Workshop participants addressed the following focus areas:

- Use of diagnostic assays during an outbreak
 - Business continuity
 - Availability and status of validated tests
- Laboratory operations during an outbreak
 - Select Agent Rule considerations
 - Utilization of Biosafety Level 2 (BSL-2) and BSL-3 facilities
- Laboratory sample and reagent prioritization
 - Sample triage and prioritization
 - Reagent prioritization and procurement
 - Activation of the National Animal Health Laboratory Network (NAHLN)

An initial agricultural screening tools workshop was held in November 2010 to formulate a definition of the term “agricultural screening tool,” evaluate the current status of agricultural screening tools, and identify gaps and requirements for protecting

the U.S. agriculture and public health sectors. During a second workshop in April 2011, participants identified and ranked their priorities for the development and use of agricultural screening tools. This report summarizes the discussions and participants' recommendations from the third workshop. Participants recommended a number of actions to assist in development of policies and for laboratory concepts of operations during an FAD outbreak. Primary recommendations include:

- Determine the processes and procedures for establishing additional laboratories to conduct confirmatory testing for foot-and-mouth disease (FMD) serology
- Revise the NAHLN checklist to reflect the minimum general biosafety and biosecurity requirements for FAD sample processing and testing
- Formalize NAHLN and NVSL representation on departmental and interagency response groups and command teams
- Maintain an inventory of NAHLN laboratories with current Select Agent Program registration and approved agents
- Define a common language for phases and types of FAD outbreaks, and case definitions
- Develop and communicate national surveillance plan options for the start of an outbreak
- Implement a national data management system that can be used pre-event, as well as during an outbreak
- Consider developing a fast track for temporary Select Agent Program registration or exemptions, based on the nature of an outbreak and the associated laboratory needs (such as for new test development, forensics, or research)

Participants discussed other critical needs for policies and laboratory concepts of operations during an FAD outbreak and identified recommendations for individual NAHLN laboratories to enhance their preparedness.

Workshop overview

This report describes the key findings, issues, and discussion points that arose during an agricultural screening tools workshop hosted by the DHS National Center for Foreign Animal and Zoonotic Disease Defense (FAZD Center) in October 2011. Participants included 44 personnel representing the FAZD Center, DHS, USDA Animal and Plant Health Inspection Service (USDA-APHIS), Iowa Department of Agriculture and Land Stewardship, Iowa Department of Natural Resources, NAHLN laboratories, university research centers, and livestock industry organizations.

Objectives

The overall workshop objective was to gather input from experts and stakeholder groups in preparation for drafting policies for the use of agricultural screening tools and further development of laboratory concepts of operations during an FAD outbreak. The workshop included presentations by subject-matter experts and subsequent group discussions. The presentations included overviews of the following programs:

- DHS agricultural screening tools
- USDA-APHIS Veterinary Services (VS) preparedness for an FAD outbreak
- Business continuity plans for the poultry, pork, and dairy industries

Participants then divided into three discussion groups (panels 1, 2, and 3) to address the following focus areas:

- Use of diagnostic assays during an outbreak
 - Business continuity

- Availability and status of validated tests for use in the United States
- Laboratory operations during an outbreak
 - Select Agent Rule considerations
 - Utilization of Biosafety Level 2 (BSL-2) and BSL-3 facilities
- Laboratory sample and reagent prioritization
 - Sample triage and prioritization
 - Reagent prioritization and procurement
 - Activation of the National Animal Health Laboratory Network (NAHLN)

At the end of the workshop, each panel presented its list of recommendations for new policies, new projects, and additional steps to support laboratory preparedness for an FAD outbreak.

Follow-up from previous workshops

The initial agricultural screening tools workshop was held in November 2010. Goals for that workshop were to formulate a definition of the term “agricultural screening tool,” evaluate the current status of agricultural screening tools, and identify the gaps in and requirements for protecting U.S. agriculture. The workshop participants defined an agricultural screening tool as:

“A tool used to detect a potential disease or condition in an animal, group of animals, or animal product. The tool may be used in any phase of an outbreak response, and is not required to be confirmatory (diagnostic) in nature, but rather is intended for rapid initial detection.”

The second agricultural screening tools workshop was held in April 2011 and focused on industry perspectives for utilizing screening tools to protect the agricultural infrastructure. Accordingly, the group of participants included leaders from the beef, dairy, swine, sheep/goat, and poultry industries. The group was tasked with creating a prioritized list of recommendations for developing and

using agricultural screening tools. As discussed and ranked during the second workshop, these priorities were to:

- Develop agricultural screening tools that can be used to permit movement of animals that don't have clinical signs of disease, especially during an outbreak or recovery period
- Validate assays that are currently being used for PCR (polymerase chain reaction) and ELISA (enzyme-linked immunosorbent assay) testing for use with additional matrices, including:
 - Milk (such as from bulk milk tanks)
 - Oral fluids (such as from saliva-drenched ropes)
 - Meat juice
 - Air and environmental samples
 - Blood, especially for testing for foot-and-mouth disease (FMD) virus
- Validate pooling of samples to test for FADs, including:
 - Optimal pooling of swabs or similar specimens for poultry diseases
 - Optimal pooling of animal blood and/or swab samples, especially for FMD detection
- Develop simple, low-cost, field-deployable devices for nucleic acid extraction and/or amplification
- Develop and validate serological tests for “disease free” testing and develop associated policies for using those tests.

In the third workshop (summarized in this report), participants were asked to develop recommendations for policies regarding the use of agricultural screening tools and laboratory concepts of operations during an FAD outbreak. In turn, these policies and concepts of operations can support the development and use of new agricultural screening tools

Highlights of the workshop discussions

The agricultural screening tools workshop began with an introductory presentation by Dr. Tammy Beckham, Director of the FAZD Center. She presented the meeting goals and objectives and an overview of results from the first two agricultural screening tools workshops. Dr. Michelle Colby, a Branch Chief with the DHS Science and Technology Directorate, then presented an overview of the DHS agricultural screening tools project. The Director of the National Veterinary Services Laboratories (NVSL), Dr. Beth Lautner, provided an overview of USDA-APHIS Veterinary Services' recent activities related to preparedness for FAD outbreaks. Next, representatives from the poultry, pork, and dairy industries presented business continuity plans for their respective industries.

Participants then split into discussion groups to address specific focus areas. These groups were:

- Panel 1: Use of diagnostic assays during an outbreak
- Panel 2: Laboratory operations during an outbreak
- Panel 3: Diagnostic sample and reagent prioritization

Panel discussions continued throughout the afternoon and the following morning. In the afternoon of the second day of the workshop, discussion leaders presented each panel's recommendations and reviewed any remaining discussion items. Lastly, the facilitator summarized the panels' presentations and described the next steps for establishing policies and enhancing the laboratory concepts of operations for agricultural screening tools.

Use of diagnostic assays during an outbreak

Panel 1, led by Dr. Elizabeth Lautner, began by listing issues that would guide their discussion on the use of agricultural screening tools and diagnostic assays during an FAD outbreak. These issues included:

- Using confirmatory tests during different phases of an outbreak
- Determining whether duplicate samples will be collected, and split between the NAHLN laboratory and NVSL for confirmatory testing (within the context of VS Memorandum 580.4)
- Using testing algorithms with and without FMD vaccination
- Identifying who develops the surveillance plan for different zones and at different phases of an outbreak
- Understanding the performance characteristics of pen-side assays to ensure appropriate use during an FAD outbreak
- Testing for movement of animals and products
- Identifying the needs for secure commodity plans to include serology testing
- Determining what tests are required in order to declare freedom from disease

The group quickly ascertained that animal health responders need a way to report and have a shared understanding of the “phases” of an outbreak. The use of diagnostic assays will vary with different outbreak phases and will be influenced by related factors, such as which commodities are involved, whether animal movement is halted or permitted, and the extent to which the disease has spread. The panel 1 discussion leader presented outbreak phases that were recently outlined at a separate policy workshop attended by officials from the NVSL, NAHLN Program Office, and the USDA-APHIS National Center for Animal Health Emergency Management (NCAHEM).

Those phases are:

- Phase 1 – Samples are sent to the NVSL Foreign Animal Disease Diagnostic Laboratory (FADDL) and to the local NAHLN laboratory. This phase will likely last only a few days.
- Phase 2 – Samples can be tested solely at the local NAHLN laboratory. Samples that test positive may be sent to FADDL for virus characterization.
- Phase 3 – A small number of samples within the control area are sent to FADDL for molecular epidemiology. FADDL will determine how many samples this should be.
- Phase 4 – Samples from outside the control area, but within the same state, may not need to be confirmed at FADDL (as determined by the Incident Command). Samples from newly infected states should be sent to FADDL.
- Phase 5 – Samples do not need to be confirmed at FADDL if FMD becomes endemic.

In general, NVSL confirmation is required for the index case and for cases occurring in new species, new geographic areas, new compartments, animals that show a change in clinical presentation, and/or if there is a suspected change in epidemiology of the virus.

While these descriptions may be a good model for laboratory response phases during an FAD outbreak, other phase definitions also exist. The NCAHEM *Foot-and-Mouth Disease Response Plan (September 2011 draft)* describes phases and types of an FMD outbreak. The laboratory response phases (above) can potentially be fit into the overall outbreak phases listed in the response plan. Accordingly, panel 1 recommended that USDA-APHIS should define a common language for phases and types of an outbreak, as well as for case definitions.

Panel 1 also discussed testing for movement and permitting. They identified three types of testing with different requirements: slaughter/sentinel testing, testing for movement, and testing for surveillance. Most of the movement testing could be conducted by

polymerase chain reaction (PCR) at NAHLN laboratories, and negative results would not need to be confirmed at NVSL. Confirmatory testing for positive results would depend on the control zone from which the samples originated. For surveillance to demonstrate freedom from disease, serology would be the primary testing method. However, reagents for these tests are currently available only at NVSL. Thus, the panel identified a need for additional confirmatory laboratories during an outbreak or to have the reagents for serological testing distributed to other laboratories. In either case, training and proficiency testing would be needed for laboratory personnel.

The group discussed “secure” movement plans that have been developed by several livestock and poultry industries. These plans include regular sampling and laboratory testing to establish a baseline herd disease status for permitting animal and/or product movement during an outbreak. While there may always be some risk to moving animals or products from control areas during an outbreak, effective planning and communication can help minimize that risk.

Laboratory operations during an outbreak

Panel 2, led by Dr. Richard Breitmeyer, began by listing issues that would guide their discussion about laboratory operations during an outbreak. These issues included:

- Biosafety containment needs
- NVSL confirmation requirements
- Biological Select Agent and Toxin issues
- Sample storage requirements
- Training for NAHLN laboratory personnel
- Logistics for handling positive samples

The panel first discussed what components of testing can be performed in BSL-2 facilities and what components of testing

require BSL-3 space. BSL-3 space is limited, and not all states have a veterinary diagnostic laboratory with BSL-3 testing capability. For those with BSL-3 laboratories, the testing capacity may be small and easily overwhelmed during an outbreak. Participants decided that each laboratory should have a plan for utilizing its BSL-2 and/or BSL-3 space, and that this plan should be in place prior to an outbreak. The plan should include steps for handling highly suspect samples at the start of an outbreak, as well as measures to ensure continuity of business for routine testing.

Participants also suggested creating a checklist for a standardized risk assessment. The risk assessment and mitigation process would be led by the NAHLN laboratory, in conjunction with the NAHLN Program Office, State Animal Health Official (SAHO), and USDA-APHIS Area Veterinarian in Charge (AVIC). The group also suggested revising the NAHLN checklist to reflect the minimum general requirements based on the outcome of the risk assessment and mitigation process.

Panel 2 discussed the requirements of the Select Agent Program and the exemptions that laboratories might request during an FAD outbreak. The panel recommended that Select Agent Program registration should not be required in order for NAHLN laboratories to perform routine diagnostic testing. However, since laboratories may need to have Select Agent Program registration to handle FAD outbreak samples, the group recommended that a “fast track” be developed for additional laboratories to be approved for handling the specific select agent. They also suggested that the NAHLN checklist should include a requirement for basic knowledge about the Select Agent Program.

The group then discussed whether enforcement of Select Agent Program rules should change during an outbreak. A Declaration of Emergency from the Secretary of Agriculture can include a directive to set some of the regulations aside. The panel recommended that a Select Agent Program exemption should be provided only to allow less-frequent reporting to the Select Agent Program office regarding positive samples from the outbreak, and to allow delayed disposal of presumptive positive samples. They recommended that any other deviations from the Select Agent

Program requirements should be pursued under the Select Agent Rule and with USDA approval.

Diagnostic sample and reagent prioritization

Panel 3, led by Dr. Jane Rooney, began by listing issues that would guide their discussion about sample and reagent prioritization during an outbreak. These issues included:

- Sample collection requirements
- Triage and prioritization of incoming samples
- Prioritization of sample reagents

For sample collection requirements, the group considered how a “high-priority” sample would be handled, and who would decide which samples would have highest priority. They also discussed the differences between high-priority and high-risk samples. This led to a discussion of the sampling requirements for wildlife, as well as for livestock, and whether those requirements would vary with different phases of an outbreak.

Panel 3 reinforced recommendations from previous laboratory response exercises that all levels of the incident command structure should include a laboratory liaison. This liaison would help the incident command team identify which samples should be highest priority for laboratory testing. The panel also suggested that pre-planning for sample collection requirements should include the SAHO, the AVIC, the NAHLN laboratory director, and industry representatives.

In a widespread FAD outbreak, testing reagents may be limited and require some allocation decisions. Particularly, requests for “wellness” testing of presumably healthy animals could consume reagents that might be needed elsewhere for higher priority samples – such as to determine the extent of an outbreak or whether animals can be moved within a control area. Panel 3 considered how incident responders should work together to prioritize the collection of samples during an outbreak. They recommended that NCAHEM convene a working group to provide

guidance and a matrix on the prioritization of diagnostic samples. During the workshop, panel 1 began working on such a matrix. The working group should consider both disease control and continuity of business needs. Thus, the focus areas connected and reinforced the discussions taking place among the three panels.

Recommendations and next steps

In the final discussion session, workshop participants were asked to submit their recommendations. Discussion leaders presented each panel's recommendations, and the group sorted the list into recommendations for new policies, new projects, and additional preparedness steps. Workshop participants recommended a number of actions to assist in development of policies for agricultural screening tools and/or laboratory concepts of operations during an FAD outbreak. Those recommendations are listed below.

Recommendations for USDA-APHIS Veterinary Services

Workshop participants recommended that USDA-APHIS Veterinary Services should:

- Use a common set of terms for outbreak phases, types, and case definitions
- Establish procedures and processes for additional laboratories to conduct confirmatory serology testing during an FAD outbreak
- Determine the number, or percentage, of samples that should be sent to confirmatory laboratories for confirmatory testing, forensics, and/or molecular epidemiology purposes
- Develop a policy and procedure for the validation of new technologies in the face of an outbreak
- Finalize a policy for differential diagnostic testing during an FAD outbreak, including the responsibility for funding and the criteria for additional diagnostic work

- Clarify how sample collection supplies will be purchased and provided to responders
- Communicate which sample types are validated for testing, and the assay performance characteristics, so that field responders can collect appropriate sample types as often as possible
- Decide and communicate which samples/cases must be confirmed at NVSL following the index case, such as cases that:
 - Originate outside the established containment area
 - Originate from a new species
 - Occur in a new geographic area (region) and/or a new industry compartment
 - Display a change in clinical presentation
 - Suggest changes in the epidemiology of the disease
- Revise the NAHLN Operational Plan to address the potential increase in the number of samples, and the risks of handling/testing those samples, at the beginning of an outbreak
- Develop a standardized risk assessment tool for laboratories to use for biosafety/biosecurity assessments, and provide training for use of that tool
- Revise the NAHLN checklist to include a requirement for staff to have basic knowledge about the Select Agent Rule
- Maintain an inventory of NAHLN laboratories with current Select Agent Program registration and approved agent
- Develop a list of individuals and organizations to be notified of NAHLN activation and deactivation, and a process for notifying them
-

- Work with the National Veterinary Stockpile program to assess whether establishing and maintaining a rolling inventory of laboratory supplies, reagents, and testing kits is feasible
- Clarify the timeline and testing requirements for notification to the World Organisation for Animal Health (OIE) regarding an FAD outbreak in the United States
- Work with the USDA Food Safety and Inspection Service (FSIS) to establish policies and a memorandum of understanding for slaughter sampling
- Work with the USDA-APHIS Wildlife Services and the Department of the Interior (DOI) to explore wildlife FAD investigations and laboratory testing
- Finalize NAHLN and NVSL representation on departmental and interagency response groups and command teams
- Develop and communicate national surveillance plan options for the start of an outbreak
- Implement a national data management system for outbreak data, which can also be used for pre-event purposes
- Explore the needs for regulatory authority regarding the use of pen-side FAD tests
- Address the outstanding and critical need to have a robust system for messaging data during an outbreak
- As soon as an outbreak is confirmed, establish the criteria for identifying actionable cases (i.e., whether clinical signs and a positive screening test are sufficient for field responders to take action)
- Work with the National Center for Import and Export (NCIE) to consider a “fast track” for Select Agent Program registration (or for temporary registration) based on the nature of an outbreak and the scientific need (such as for diagnostic, forensic, or research purposes)

- Work with the NCIE to review the NAHLN checklist to see if laboratories can qualify for Select Agent Program exemption based on compliance with NAHLN standards
- Ensure that the incident command structure for an FAD outbreak includes, at all levels, a laboratory liaison position
- Develop training materials about NVSL and NAHLN processes and procedures that can be provided as new incident command teams and personnel arrive to staff the Area Command and/or multi-agency management teams at the federal level
- Establish a working group to develop a matrix or other tool to help prioritize diagnostic samples during an FAD outbreak
- Educate stakeholders about the differences in high-priority and high-risk samples. For example, diagnostic samples collected for business continuity purposes may be high priority but not high risk, because they are presumed to be negative.
- Convene a working group to provide guidance to the National Incident Management Team and NAHLN regarding prioritization of reagents

Recommendations for NAHLN laboratories

Workshop participants recommended that individual NAHLN laboratories should:

- Develop a plan for utilizing the NAHLN laboratory's BSL-2 and/or BSL-3 space for sample processing and testing prior to an outbreak
- Pursue an exemption from the Select Agent Rule only for official reporting to the Select Agent Program and to allow delayed disposal of presumptive positive samples. Any other deviations should be pursued under existing

guidelines for the Select Agent rule and with USDA approval

- Self-report their Select Agent Program registration status and which select agents are included to the NAHLN Program Office
- Provide Select Agent training to any personnel who transfer into their facility during an outbreak, if registered with the Select Agent Program
- Develop training materials about laboratory processes and procedures that can be provided as new incident command teams and personnel arrive

Workshop participants also discussed the critical need for an information technology infrastructure to provide communications and links between databases, for reporting laboratory test results. This same recommendation has risen out of other forums, such as recent tabletop exercises for the NAHLN and NVSL and previous agricultural screening tools workshops. Participants noted that the current information technology systems do not support linking the test results that are reported from state and federal laboratories. Agricultural screening tools would present additional results that need to be reported in a timely manner and linked with identification codes for both the animals/premises being tested and the laboratory providing confirmatory results. Thus, a robust information technology infrastructure is also critical for the full, efficient, and effective use of agricultural screening tools.

The FAZD Center plans to host additional workshops in the coming year to bring together subject-matter experts, industry leaders, and policy-makers to discuss pressing needs and gaps in foreign animal and zoonotic disease defense. Continued input from all of these groups will enhance the resiliency of production agriculture in the event of a foreign animal disease outbreak.

Appendix: Workshop participants

Name	Organization	Panel
Bruce Akey	Executive Director for Animal Health Diagnostic Center, Cornell University	1
Lowell Anderson	Assistant Area Veterinarian in Charge, USDA-APHIS	3
Claire Andreasen	Professor and Associate Dean, College of Veterinary Medicine, Iowa State University	1
Tammy Beckham	Director, FAZD Center and Texas Veterinary Medical Diagnostic Laboratory (TVMDL)	1
Troy Bigelow	Swine Disease Staff Officer, USDA-APHIS	1
Richard Breitmeyer	Director, California Animal Health and Food Safety Laboratory System	2 (Leader)
Alfonso Clavijo	Biological Systems Co-Theme Leader, FAZD Center	2
Matthew Coats	Program Manager, Office of University Programs, DHS	3
Michelle Colby	Branch Chief, Agricultural Defense, Science and Technology Directorate, DHS	2
Geoffrey Dennis	Research Assistant, Center for Plant Health Science and Technology, USDA-APHIS	2
Larry Elsken	Global Vaccine Manager, Center for Veterinary Biologics (CVB), USDA-APHIS	3
Angela Ervin	Program Manager, Science and Technology Directorate, DHS	1
Dale Garner	Wildlife Division, Iowa Department of Natural Resources	3
Stephen Goff	Area Emergency Coordinator, USDA-APHIS	3

Bruce Harper	Director of Science, Plum Island Animal Disease Center, DHS	1
Sharon Hietala	Professor, University of California- Davis	1
Diane Holder	Microbiologist, USDA-APHIS	1
Freeda Isaac	National Center for Import and Export, USDA-APHIS	2
Barbara Kamicker	Senior Life Scientist, SAIC	1
Elizabeth Lautner	Director, National Veterinary Services Laboratories, USDA-APHIS	1 (Leader)
Christie Loiacono	Associate Coordinator, NAHLN, USDA-APHIS	2
Barb Martin	Coordinator, NAHLN, USDA-APHIS	3
Lianne Moore	Program Coordinator, Office of University Programs, DHS	3
Igor Morozov	Science Manager, DHS Center of Excellence for Emerging Zoonotic and Animal Diseases (CEEZAD), Kansas State University	1
Stacy Morris	Chief of Staff, FAZD Center	NA
Regg Neiger	Pathologist, Animal Disease Research and Diagnostic Laboratory, South Dakota State University	1
Jan Pedersen	Microbiologist, Diagnostic Virology Laboratory, NVSL, USDA-APHIS	1
Kevin Petersburg	Area Veterinarian in Charge, USDA-APHIS	2
David Pyburn	National Trichinae Coordinator, USDA-APHIS	1
Jennifer Rinderknecht	Research Associate, FAZD Center	3
Jane Rooney	Veterinary Medical Officer, NCAHEM, USDA-APHIS	3 (Leader)
Jim Roth	Director, Center for Food Security and Public Health, Iowa State University	1
Beverly Schmitt	Director, Virology Laboratory, NVSL, USDA-APHIS	2

Dave Schmitt	State Veterinarian, Iowa Department of Agriculture	2
Harry Snelson	Director of Communications, American Association of Swine Veterinarians	3
Rosemary Speers	Principal Research Scientist, CNA	NA
Darrel Styles	Senior Veterinary Officer, NCAHEM, USDA-APHIS	3
Alex Thompson	Assistant Director, National Surveillance Unit, USDA-APHIS	1
Sarah Tomlinson	Associate Coordinator, NAHLN, USDA-APHIS	1
Fernando Torres-Velez	Diagnostic Services Section Head, FADDL, USDA-APHIS	1
Darrell Trampel	Professor, Iowa State University	1
Patrick Webb	Swine Health Programs, National Pork Board	1
Jon Zack	NCAHEM, USDA-APHIS	1
Anne Marie Zaudtke	Consultant, Booz Allen Hamilton	2