

National Animal Health Laboratory Network Action Plan

Issue Group: Laboratory Systems

Specific Activity Area being addressed by this Action Plan: Direct and promote the National Animal Health Laboratory Network that serves as the world leader in veterinary diagnostics.

Safeguarding Review Recommendations Covered:

17. Define the role of the NVSL as the reference laboratory in support of the NSS.

18. Upgrade the capabilities of the NVSL and the CVB for their critical role in the surveillance system.

73. Seek funding to address the diagnostic and applied research needs for FADD activities, including the establishment and maintenance of Biosafety Level (BSL) 3-AG and BSL 4 laboratory facilities. **(also included under Funding)*

74. Direct funding towards establishing the expertise and physical capabilities at state diagnostic laboratories to perform diagnostic testing for FAD in the event of a confirmed outbreak.

118. Define roles and responsibilities of federal and state laboratories in the national laboratory infrastructure, including roles in FAD testing.

119. Develop and implement a quality assurance and control system for both federal and state laboratories that meets or exceeds international standards. Maintain and disseminate an active database of laboratories meeting these standards.

121. Utilize previous NVSL reviews in conducting a needs assessment of the National Laboratory System regarding emergency diagnosis and applied research. Implement a plan that supports the immediate and long-term needs of the National Laboratory System.

Issue Group Findings:

Capacity is currently lacking for optimal surveillance activities and for surges in testing needs. There remains a need for full implementation of the National Animal Health Laboratory Network. The partnership between NVSL and networked state laboratories to expand capacity, including redundancy, development of secure reporting communications, and identification of needs for expertise requires resources and expansion. There is a need to define the roles of NVSL as an accredited reference laboratory and the network laboratories.

ARS was awarded six million dollars to develop and validate assays jointly with Veterinary Services for eight diseases which will ultimately be deployed to the NAHLN -

(Foot and Mouth Disease, Rinderpest, Contagious Bovine Pleuropneumonia, Lumpy Skin Disease, Classical Swine Fever, African Swine Fever, Highly Pathogenic Avian Influenza and Exotic Newcastle Disease). A Vesicular Stomatitis assay has been developed and is in the validation process. The NAHLN Steering Committee is exploring other diseases for test development.

FY2004 CSREES Homeland Security budget line contains \$3.7 million for maintenance of NAHLN labs. (\$308,500 per lab) The FY 2005 Presidents budget contains a CSREES Homeland Security line of \$30 million. The NVSL Veterinary Diagnostics budget lines increases in FY 2003-2004 and FY 2005-2006 requests were justified by and targeted to NAHLN activities (Training, Proficiency tests and no cost reagents). CCC emergency funding is being used to equip and provide fee for service payments to networks of disease specific labs for national surveillance. (30 END labs, 27 CWD labs and 12 BSE labs)

A NAHLN Steering Committee was formed in March, 2003. The committee consists of CSREES representatives, NVSL Director, AAVLD President, two NAHLN Laboratory Directors, a Non-NAHLN Laboratory Director, a representative from USAHA, the FADDL Chief and the NAHLN Coordinator. The Steering committee has established criteria for NAHLN membership and policies. Dr. David Kinker acted as the interim NAHLN Coordinator since the Steering Committee formed. A full time NAHLN Coordinator position was created and filled by Barbara Martin in August, 2004.

NAHLN Assays – Pilot NAHLN labs had personnel trained in FMDV Ag-ELISA in FY 2003. Field validation and training on real time PCR for HPAI, END, FMDV and CSF along with proficiency testing have been accomplished and deployment of the END and AI assays occurred early FY 2004 with FMDV and CSF projected by early in FY 2005. Target deployment dates have been established for other disease assays, African Swine Fever – FY 2005, Rinderpest and Lumpy Skin Disease – FY 2006. An assay for CBPP is being developed and will be validated when it is available. Initial discussions have been held with the National Surveillance Unit to determine how to deploy the CSF and FMDV assays.

NAHLN Communication, Alert and Reporting Tools are being assessed through the Safeguarding Information Technology Issue Group. A steering committee has been established, standards for messaging, vocabulary and test descriptions have been agreed upon. A contract for a needs analysis and development of a Pilot NAHLN IT system was accomplished in 2003. The pilot was delivered to four network labs and NVSL in February with user testing ongoing. With over \$1 M of END CCC funds, BSE CCC funds, and NVSL Diagnostic appropriated funding, the tool has been developed further and a Change Control Board, made up of State, Federal, and Information Technology personnel, has been established. This Board is responsible for providing advice on design expansion and prioritizing any needed changes for the tool. Linkages with FSIS, CDC and DHS are being planned.

Building and funding on the Ames Modernization Project has continued to make progress. The last \$178 million of the current total \$460 million has been submitted in the Presidents FY 2005 budget request. These new facilities will enhance the nations' response and recovery from a national animal health event and support the role of NVSL as the reference lab for the NAHLN.

Proposed Actions:

A National Animal Health Laboratory Network requires a process for development, validation and implementation in order to gain international acceptance. Appropriate testing technology will be transferred to networked laboratories for detection, surveillance, exclusion, and international movement purposes. Reliable results are assured through quality assurance guidelines and proficiency test panels. Test results are communicated through a secure communications network to those that need the information. This system, melding federal and state resources will provide the infrastructure needed for an effective response and recovery from an animal disease outbreak and promote the United States as a world leader in animal health.

Major action categories:

1. Continue to support the development and expansion on the NAHLN and continue to support the efforts and goals of the NAHLN Steering Committee.
2. Strengthen standard criteria for laboratory and assay selection
3. Structure the compliance (quality assurance) and maintenance (assessing program needs) of participating laboratories
4. Ensure long-term funding
5. Develop a communication plan for NAHLN activities
6. Ensure NAHLN surveillance activities are evaluated to ensure that problems of animal health importance are being monitored efficiently and effectively. Animal health surveillance systems should be evaluated periodically, and the evaluation should include recommendations for improving quality, efficiency, and usefulness.
7. Explore linkages with FSIS, CDC, DHS and other agencies and Departments (to include wildlife).

Implementation Plan:

1. Continue to support the development and expansion on the NAHLN and continue to support the efforts and goals of the NAHLN Steering Committee.
Responsible individual/group: Veterinary Services Management
Timeline: Ongoing
2. Develop Uniform Methods and Rules (UM&R) or equivalent document for NAHLN as part of a comprehensive performance management plan
 - a. Strengthen science and program needs based criteria for laboratory and assay selection
 - i. Define the roles and responsibilities for the NVSL as the reference laboratory and the network laboratories.
 - ii. Identify application process and authority for lab approval
 - iii. Create subject matter expert review process for assay selection and use

Responsible individual/group: NAHLN Coordinator/NAHLN Steering Committee

Timeline: Draft UM&R or equivalent document completed by end of CY 2004; followed by stakeholder review

3. Structure the compliance (quality assurance) and maintenance (assessing program needs) of the networked laboratories

Responsible individual/group: NAHLN Coordinator/NAHLN Steering Committee

Timeline: Draft UM&R or equivalent document completed by end of CY 2004; followed by stakeholder review

4. Ensure long-term funding
 - a. Determine out-year budget needs for NAHLN
 - b. Communicate budget needs to stakeholders and within USDA
 - c. Explore potential/alternative funding sources
 - d. Investigate whether NAHLN should be its own Veterinary Services line item

Responsible individual/group: NAHLN Coordinator/NVSL Director/VS Deputy Administrator/CSREES

Timeline: Out-year budgets identified by March 2005

5. Develop a communication plan for NAHLN activities
 - a. Devote LPA resources for timely communication activities
 - b. Develop and maintain a public NAHLN website

Responsible individual/group: NAHLN Coordinator/NAHLN Steering Committee/LPA

Timeline: Communication tools and website developed by January 2005

6. Ensure NAHLN surveillance activities are evaluated to ensure that problems of animal health importance are being monitored efficiently and effectively. Animal health surveillance systems should be evaluated periodically, and the evaluation should include recommendations for improving quality, efficiency, and usefulness.

- a. Utilize established and/or develop guidelines for evaluating animal health surveillance systems

Responsible individual/group: NAHLN Coordinator/NAHLN Steering Committee/NSS

Timeline: Ongoing

7. Explore linkages with FSIS, CDC, DHS, and other agencies and Departments (to include wildlife)

Responsible individual/group: NAHLN Coordinator/NAHLN Steering Committee/NSS

Timeline: Ongoing

Resources Needed

Current estimates include \$74 million for the NAHLN start up costs (\$52 million pass through funding to the state network labs and \$22 million for NVSL) and \$22 million for annual maintenance costs.

The NVSL funding is for reagents, proficiency testing programs, data review, SOP development, equipment, coordination staffing functions, IT modernization and to establish and startup surveillance systems. The state networked lab funding is for facility upgrades, disposal capacity for high volume testing, personnel, training and equipment.

Development of a Uniform Methods and Rules by existing personnel and Steering Committee will require funding for meetings and travel - \$50,000

Development of a communication plan and public website – 0.5 FTE GS11/12 \$39,997 plus travel - \$15,000. Total Year 1 - \$55,000

Statutory/Regulatory Impacts

No impacts currently foreseen.

Political Sensitivities

In order to adequately support and effectively administer the NAHLN, laboratory participation may need to be limited. The criteria for the selection of participating laboratories and deployment of assays need to be transparent as incorporation into the network brings responsibilities and funding to the laboratories that are highly visible to stakeholders, political and business interests.

Sequencing

Activities identified by the Information Technology Issue Group significantly impact the success of this action plan, and the implementation of the NAHLN greatly impacts the success of other action plans that involve veterinary diagnostic testing. The Safeguarding Lab System group's action plans on quality assurance and test validation should be executed in parallel with NAHLN development.

Partnering/Cooperation/Communication:

The development of the UM&R or equivalent document involves obtaining input from partners which include States, industry, other Federal agencies, etc.

Expected Outcome and Performance Indicators:

Expected Outcomes: Successful implementation of this action plan will continue the establishment and maintenance of the NAHLN and will result in stable funding available for NAHLN activities, publication of a NAHLN UM&R or equivalent document and effective communication of NAHLN activities to stakeholders. The NAHLN is meeting program needs and prepared to provide diagnostic services in the event of a national adverse animal health emergency.

Measure: Published UM&R or equivalent document, functional & maintained NAHLN public website, communication tools are in place

Linkage to the VS Strategic Plan:

Full development of the NAHLN will be consistent with several Strategic Plan Goals and Objectives.

Objective 1.3 – “Improve readiness to respond to disease incursions.”

Objective 2.1 – “Rapidly detect and evaluate foreign and emerging animal diseases including those with public health/food safety implications.”

Objective 2.6 – “Improve laboratory diagnostic services, products and training to support animal disease surveillance.”

Objective 3.2 – “Ensure the nationwide availability of adequate laboratory capacity to support animal disease investigations and control and eradication programs.”

Objective 4.4 – “Improve diagnostic testing associated with the marketing of animals and animal products.”